broader community of practicing urologists. To the extent that technology substitution occurs, the use of URS might be expected to change after the expansion of lithotripter ownership.

MATERIAL AND METHODS

Data Source and Subjects

For the present study, we used data from the Healthcare Cost and Use Project's State Ambulatory Surgery Database (SASD). The Michigan SASD files capture 96% of hospital-based surgeries in a given year performed on the same day in which patients are admitted and released.[11] The completeness of the SASD has been validated through alternative sources of comparative data.[11]

Using the *Current Procedural Terminology* codes (52320, 52325, 52330, 52335, 52336, 52337, 52351, 52352, and 52353), we identified patients undergoing URS from 2004 to 2007. Before 2005, the SASD's state partner did not supply outpatient information from 2 health systems in Michigan, which accounted for 4% of all discharges. Therefore, we limited our study population to those discharges from hospitals with complete reporting during the study interval, as determined by the SASD's unique hospital identifier.

Primary Outcome

We then calculated the annual state-level rates of URS use. The numerator for our rate calculation was the number of times that URS was performed in Michigan during a specific calendar year. The denominator represented the number of people living within Michigan that year. We obtained our population estimates from the *Dartmouth Atlas of Health Care*.[12] We adjusted all rates of URS by age and sex to the 2000 US population using direct standardization and expressed them per 100 000.

Statistical Analysis

From 2005 to 2006, United Health Systems and American Kidney Stone Management formed Michigan subsidiaries. Although the individual shares have not been publicly disclosed, personal communications with 1 of the 2 lithotripsy providers suggests that more than one half of urologists in the state (the American Urological Association database currently shows 390 practicing urologists members/nonmembers) elected to participate in these partnerships. Owing to Michigan's stringent Certificate of Need requirements,[13] urologist investment in lithotripsy units had previously been limited. From this information, we defined 2 periods—before (2004) and after (2007) the expansion of lithotripter ownership.

As an initial analytical step, we examined the differences between patients who underwent URS across the 2 periods. We compared a variety of demographic characteristics (eg, patient age, sex, race, primary payer, socioeconomic status, and comorbidity status). We used a composite measure to assess socioeconomic status at the patient zip code level,[14] producing 3 equal-size groups (terciles) that ranged from low to high. To assess comorbidities, we derived a weighted Charlson score for each patient.[15] For these comparisons, we used parametric and nonparametric statistics, as appropriate. Next, we plotted the rates of URS use in Michigan by calendar year. We fitted a linear regression model to evaluate for significant changes in URS use over time. Finally, to account for potential confounding by national trends in URS practice patterns, we used linear regression analysis to compare the trends in the rates of URS use in Michigan with those from Florida during the study interval. Florida was selected for comparison because of its high number of annual ambulatory surgery discharges among states in the SASD.[16] In addition, Florida does not subject medical facilities to Certificate of Need requirements,[17] yielding a likely stable penetration of physician-owned lithotripsy units during this period compared with Michigan.

For all statistical inferences, we performed 2-sided significance testing and set a type I error rate at 0.05, using the SAS system, version 9.2 (SAS Institute, Cary, NC). The University institutional review board of Michigan deemed that our study on these existing, publicly available data was exempt from its oversight.

RESULTS

In 2004 and 2007, 5857 and 6294 URSs were performed at hospital-based outpatient departments, respectively (Table 1). Compared with patients treated before ownership expansion, those who underwent URS after ownership expansion were older (50.4 ± 16.0 years vs 51.3 ± 16.3 years; $P < .001$). They were also less likely to be white (93.6% vs 89.1%; $P < .001$) or have private health insurance (70.2% vs 66.8%, $P < .001$). In addition, they were sicker (eg, the proportion of patients with a Charlson score of zero fell from 84.3% to 80.4%; $P < .001$).

As Figure 1 illustrates, the rates of URS use in Michigan remained relatively flat between 2004 and 2007 ($P = .129$ for temporal trend). Although the absolute rates of URS use in Michigan were greater than those in Florida throughout the study interval (Fig. 1), no differences were found in the rate of change of URS use between the 2 states during the study period ($P = .479$).

COMMENT

During the past decade, physician investment in lithotripsy ventures has become an important practice component for most urologists in the United States.[3] Although these financial arrangements might incentivize providers to perform more SWL,[4,5] the potential spillover effects on competing technologies (ie, URS) remain unclear. During a period of ownership expansion of lithotripsy units among urologists in Michigan, we found that the rates of URS use remained stable during the study interval. As a secondary finding, patients treated with URS after lithotripter ownership expansion were older

Table 1. Demographic patient characteristics stratified by URS use before and after expansion of lithotripter ownership in Michigan

Characteristic	Before Ownership Expansion	After Ownership Expansion	*P* Value
Procedures (n)	5857	6294	
Patient age (y)	50.35 ± 16.02	51.34 ± 16.34	< .001
Women (%)	43.7	45.10	.121
Race (%)			< .001
White	93.6	89.1	
Black	4.1	5.9	
Hispanic	0.7	0.6	
Asian	0.6	0.6	
Other	1.0	3.8	
Primary payer (%)			< .001
Medicare	21.7	23.6	
Medicaid	5.0	5.8	
Private	70.2	66.8	
Self-pay	2.0	2.8	
Other	1.1	1.0	
Socioeconomic status (%)			.388
Low	33.3	32.5	
Medium	31.8	32.9	
High	34.9	34.6	
Charlson score (%)			< .001
0	84.3	80.4	
1	10.8	13.4	
2	3.2	4.7	
≥3	1.7	1.5	

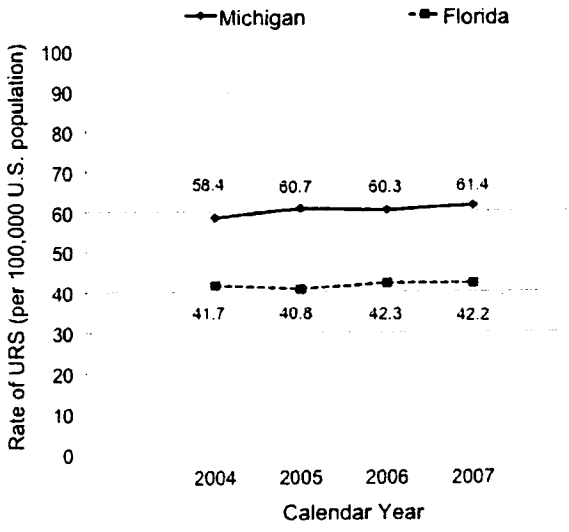

Figure 1. Trends in rates of URS use over time for Michigan and Florida.

and sicker and less likely to have private insurance than the patients treated with URS before the availability of these partnerships.

Although ownership arrangements have been linked to increased procedure use,[4-10] the extent to which the increased use might influence substitutable technologies remains largely unknown. Previously, Mitchell et al[8] analyzed medical claims from the largest worker's compensation insurer in Oklahoma. After identifying episodes of care for injured workers with a primary diagnosis of back/spine disorders, she compared the practice patterns of physician owners of specialty hospitals in Oklahoma, before and after their acquisition of ownership, to the practice patterns of physician nonowners who managed similar cases. She demonstrated that the referral rate for complex spinal fusion grew much more rapidly for owners than for nonowners. Although the use of simple spinal fusion—a less profitable, yet comparably effective, procedure[18]—grew among patients treated by nonowners, the use of this procedure decreased among owners. In contrast to Mitchell's findings, we observed stable rates of URS after the expansion of mobile lithotripter ownership, suggesting that patients in Michigan continued to receive URS when indicated despite the financial incentives for urologists to perform SWL.

Although the absolute rate of URS remained stable, the profile of patients undergoing this procedure changed during the study interval. Compared with patients treated with URS in 2004, those who underwent URS in 2007 tended to be older and sicker. There were also lower proportions of white patients and those with private health insurance. This appeared to counterbalance the shifting patient demographic (ie, younger, healthier, and wealthier patients) observed among those treated with SWL in Florida during a period of increased urologist ownership of ASCs.[4] Taken together, these changes are consistent with the migration of healthier and more profitable patients from hospitals to physician-owned facilities.[19] Although we could not exclude the possibility that this might also reflect more global changes in the population of patients with urolithiasis,[20] our findings suggest that physician ownership might also influence treatment decisions in the context of other patient considerations (eg, insurance status, pre-existing comorbidity).

Our study has several caveats. Our analysis was largely based on the assumption that SWL and URS are substitutable technologies. Although both trial and observational data suggest comparable efficacy for a variety of clinical situations,[21,22] several nonclinical factors, which we could not measure with administrative data (eg, physician training, patient preference), could also affect treatment selection.[23] While certain clinical scenarios might exist in which 1 technique would be preferable to the other, both SWL and URS are considered first-line treatment options for urolithiasis by both the American Urological Association and the European Association of Urology, further supporting our assumption that these surgical approaches are largely substitutable.[22] Further, we could not exclude the possibility of technology substitution between SWL and percutaneous nephrolithotomy or medical expulsive therapy, but the potential effect from technology substitution with these modalities would likely be marginal compared with URS, given their specific indications and the reportedly low use of these modalities during the study interval.[24,25] Additionally, because the Michigan SASD files provide discharge-level data, we were unable to account for previous stone treatment. As such, it is possible that the observed URS trend reflects a decrease in first-line URS use and an increase in secondary URS use for SWL treatment failure. However, a substantially greater increase in SWL use than that previously observed after ownership expansion would be needed to conceal the occurrence of technology substitution from the reported rates of treatment failure and salvage URS after SWL.[4,5,21,22]

Our analysis was also limited by the exclusion of ASC discharges from the Michigan SASD files. Because SWL is commonly performed in ASCs, we were unable to assess for concurrent changes in SWL use during this period of ownership expansion. However, the link between physician ownership and increased SWL rates has been previously described,[4] and we would expect similar increases in Michigan. In contrast, URS is performed predominantly in hospital-based outpatient departments, even among states with more lenient Certificate of Need requirements.[26] Moreover, ownership expansion in the present study pertained to a specific procedure rather than an entire surgical facility. Thus, the absence of ASC discharges is unlikely to have affected the validity of our findings as it relates to URS, especially in Michigan, where the establishment of ASCs is more restricted.

In addition to these considerations, the association between the rates of URS and the expansion of lithotripter ownership could be attenuated by the temporal trends affecting all states similarly. Because the annualized national trends data for URS during the study interval were lacking, we compared URS use in Michigan with the rates from Florida during the same period. Despite the absolute difference in URS rates between the 2 States, which likely reflects differing practice patterns or stone prevalence, we noted no difference in overall trends, addressing the potential bias from temporal changes in the surgical treatment of urolithiasis. We also lacked surgeon identifiers and were unable to measure the change in frequency of URS use among individual urologists who obtained ownership shares in SWL compared with those who did not. Additional studies are needed to assess the effect of ownership expansion and technology substitution at a physician level.

These limitations notwithstanding, our findings have direct implications, not only on urologists' ownership of lithotripters, but also on their investment in ancillary services technology and specialty care, facilities. Recently, high-profile articles in the lay press have raised questions about urologists who have begun buying multimillion dollar intensity-modulated radiotherapy equipment and software.[27,28] Given the substantial profit margin seen with intensity-modulated radiotherapy, critics have warned that urologist ownership could lead to its overuse.[29,30] Additionally, they have argued that urologist ownership could lead to subsequent decreases in the use of other first-line therapies for organ-confined prostate cancer, including radioactive seed implants, radical prostatectomy, and active surveillance (ie, technology substitution). These concerns have been voiced before the Centers for Medicare and Medicaid Services.[31] Although the profile of patients receiving specific treatments could change, the results of our analysis might, for the time being, help allay the latter concern regarding the use of substitutable technologies, at least at a population-level.

CONCLUSIONS

The expansion of lithotripter ownership in Michigan was not associated with decreased rates of URS but might have influenced treatment decisions among certain patient groups. Despite recent concerns, physician ownership does not appear to result in technology substitution to a substantial degree, at least as it pertains to lithotripter ownership. Although reassuring, future studies that focus on the practice patterns of individual urologists during periods of ownership expansion are still needed to better characterize the effect of physician ownership.

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EDITORIAL COMMENT

Urologists are coming under close scrutiny by third-party payers and the government for their ownership of ancillary services, including laboratory services such as blood work and pathology, imaging equipment, treatment facilities including surgicenters, lithotripters, and intensity-modulated radiation therapy. These relationships have not gone unnoticed in the lay press and are frequently recounted on the front pages of the nation's more prominent newspapers. In this article, Hollingsworth and colleagues at the University of Michigan looked at whether urologist investment in lithotripters in the state of Michigan changed practice patterns, specifically with regard to ureteroscopy (URS) and shock wave lithotripsy (SWL). The authors queried the state's ambulatory surgery database to perform their study. I found it interesting that more than half of the urologists in the state of Michigan participated in these limited SWL partnerships. Interestingly, the rate of URS compared with SWL did not change after urologists became financial partners. There were some differences in race, insurance, and comorbidities that were noted between the URS and SWL groups that were not well explained but may be simply because the uninsured may be seen more often at academic institutions or that older patients are more often anticoagulated, making them better suited for ureteroscopy. Interestingly, when compared with Florida, URS was more prevalent in Michigan, But similar differences would probably be noted for surgery compared with external beam radiation or brachytherapy for the treatment of prostate cancer.

Urologists have always been at the forefront of medical and financial innovation. I have always found it interesting to note the national and international trends in the diagnosis and treatment of all urological disorders. Urologists owe it to their field, their forefathers, and, most importantly, their patients to uphold the values of proper patient care while pushing the envelope with innovative medical advances that have made this specialty great. Under increasing governmental scrutiny, the onus will be on urologists to show that they have their patients—not their pocketbooks—in mind when they select a treatment. Hollingsworth and colleagues should be applauded for asking the tough but obvious questions for which everyone wants to know the answers.

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Dear Ms. Engleman:

I am writing again, because I want to be clear about the basis of my complaint about UESWL. It is about the nature and critical importance of patient ***consent***. If the FDA wants to hedge an issue as important as safety of a so-called "promising" technology, then fine, but then the medical community MUST BE ENTIRELY FORTHRIGHT about it with their patients. Physicians will always make professional judgments in offering therapies to their patients, but when there are alternatives to a therapy a physician is promoting, not offering clear, honest, and comparative information about both risks and benefits of all available treatments due to obvious personal non-clinical preferences, i.e. improper financial incentives, is a very serious breach of trust for patient care. Deliberately avoiding calculation of serious risks based on known, established problems with a procedure/technology is proving harmful beyond measure. Government authorities turning a blind eye to this is a very dangerous and slippery slope.

For example: Were a patient to have a tumor, polyp, or bowling ball lodged in their maxillary sinus cavity, it may be possible to perform surgery through the nose to remove it, with inherent risks. So, let's say a fancy new technology came along that eliminated the need to perform surgery, where a device was positioned over the sinus cavity externally that could emit rays that would effectively break up the tumor, polyp, or bowling ball, so that when finished all the patient need do is with a few honking blows of the nose expel the remains of their problem onto a handkerchief or tissue. Voila! "Non-Invasive!"

Now then, it turned out that one of the unpredictable problems with this new technology was that it was also found to damage, say, the optic nerve or retina of the eye, or even cause some slight brain damage. Sometimes blindness in the affected eye was immediate, but sometimes it took a while for the problem to reveal itself. Like with UESWL, the physicians performing this new sinus treatment became non-provider "investors" in the technology and based the "structures" of their "arrangements" entirely on profiting from the volume of patients they treated. What if you were the patient? Would you want to be informed? Or would you simply let the doctor decide without knowing his ulterior motivations?

With UESWL, the judgment made by urologists, the rationalizing story they tell themselves over and over again is that "patients can survive with one kidney," so they never fully or accurately disclose the actual risk to their patients from pure fear of harm to their "passive income." (And we know they never accurately disclose what it might be doing to the pancreas, spleen, etc.) My point is this: What if these hypothetical ENT sinus therapy "investor-physicians" made that same sort of judgment without disclosing the risk of blindness or brain damage because they also knew that "patients can survive with one eye or a little brain damage?" In both cases of UESWL and the hypothetical new sinus technology, patients would be unwittingly consenting to a physician's judgment that was dangerously flawed and biased to whether or not a patient would "survive" with one kidney or eye, rather than engaging the patient without bias in a proper contract for consent based on factual science or lack thereof.

Patient consent is in fact a CONTRACT, an agreement. But, it is entirely based on proper HONEST representations just like any other contract – it is insane that we are permitting the gross misrepresentations about this UESWL procedure to continue. It is easily and obviously a breach of CONTRACT with these millions of patients. It is absolutely INSANE.

Now, I just want to say this to you: Would the FDA consider this new hypothetical sinus technology safe? Or would the FDA require those performing the procedure to fully and honestly disclose the risk of blindness to the patient?

Whether a kidney or eye, we all know we could "survive" with one – but the real judgment should be made when patients decide whether or not they wish the quality of their lives to be so reduced in this manner or whether or not they prefer an alternative treatment. And when it comes to the pancreas in the case of UESWL, we have only one. This is about utilizing a valid body of honestly proven FACTS and representations, and then patients CONSENTING to them, unvarnished – this is my point. THE FACTS MATTER and "safety" is not only whether or not a patient can merely "survive" in some sort of reductionist manner. Just how do you propose to measure "survival?" Five years? Ten? Twenty? Would it depend on the age of the patient consenting to the procedure? What risk did Fen Phen pose, for example, when we figured out it was wrecking heart valves and muscle? A patient could "survive" with a valve replacement or a transplant... but was that safe?

And so this is my point. I have watched now over all these years this very grave medical injustice continuing to be leveled against the public, while the perpetrating urologists profit in their so-called "lawfully structured" financial operations that are in all honesty full blown kickbacks paid within cooperative arrangements for their patient referrals. What on earth makes these urologists so special that they are permitted to do this to people?

Are you going to do something? This whole scam is deeply unjust on a scale so massive that it is difficult to measure. It is an appalling, disgraceful, breach of medical trust with the American public, costing life, life quality and health to hundreds of thousands without their knowledge, and billions of dollars from the system to those who have been duped by a con that has reduced us to unwitting pawns in this slimy covert extortion scheme. It is disgusting and truly frightening that it has been allowed to continue without remotely appropriate legal boundaries and proper scientific measure.

Does all this mean it will be ***okay*** in the future if we start leveling one-eyed blindness across the country because people could "survive" with the other eye? Do you know how ludicrous this sounds? Now then, is it ***okay*** to knock off the function of one kidney (or spleen, or pancreas!) because people can "survive" with the other kidney (or for a while on dialysis?!)?

These urologists have not proven to be FAIR judges or practitioners of honest medicine, and have been hiding a very deadly secret for decades in order to protect their little "side" businesses. They are being permitted to just hide within the massive "herd" they have created for their own protection, paying politicians off along their merry way.

Please, I am begging you; the least you can do is give the public FAIR WARNING about what is and what has been happening to them for the past thirty years!

Please. And thank you.

Sincerely,

11-CV-10090

HON VICTORIA ROBERTS

000095

Anne Mitchell

Sent via email

6/26/14

Dear Ms. Engleman:

I recently reviewed a letter I sent to you on February 10, 2014 (attached), and am unsure whether I was clear enough about my most important concerns as I'd conveyed them to you. So, I am writing you today in attempt to clarify my point.

In the article I'd mentioned (attached), the urologists obtained certain data from *State Ambulatory Surgery Database (SASD)*. These doctors carefully selected the only the data they felt would serve to support the conclusions they had clearly already set out to reach from the beginning. Had they chosen to portray the reality and truth of this clinical situation, they could easily have used the *SASD* database to compare the numbers all around as they should have in order to have painted an honest picture of what happens in these lithotripsy "structured arrangements" before and after. In a truthful and statistically significant manner they should have portrayed (1) the volume of patients treated with UESWL before and after being financially incented to perform UESWL; (2) the volume of patients treated with URS before and after, and of utmost clinical importance (3) the volume of patients treated first by UESWL and subsequently with URS (as a remedy for UESWL failure) before and after. To be honest and forthright they should have considered and described the increase in cost to the system as a result. All these data were available to them through the SASD and the Michigan Department of Community Health Certificate of Need Section Survey Data (this survey data remains and past surveys can be requested of the MDCH CON – go to www.michigan.gov/con and click on "Annual Surveys"). But rather than draw truthful and meaningful conclusions, they chose to deceive the medical community about the truth. The truth, had they chosen it, would have clearly demonstrated the distinct and glaring corrupting of medical judgment by kickbacks at dramatically increased consumer cost in both life and treasure.

This Michigan information is very important because of the timing of it – it is still possible there to gain the knowledge of what happens to patients before and after kickback "arrangements" are "structured," and implemented. In nearly all other places in the U.S., this ship has sailed long ago – these "arrangements" have been made in most other places as far back as 1984. In Michigan today you can see the pattern of what happened elsewhere long ago. And it shows a sobering and frightening paradigm example of how medical judgment is swiftly corrupted and overtaken by greed – this greed and improper judgment goes into overdrive *especially* and even more so when "arrangements" are purported to be properly "structured." Unfortunately for the rest of us peons this is now an entrenched, highly organized, and collective greed that is intentionally protecting critical information about the truth concerning highly questionable safety of UESWL.

These urologists, on a national scale, collaborated and colluded in this UESWL scheme from the beginning and the patterns of this can easily be seen throughout the medical literature if you know what you are looking at. By being successful in absence of oversight or scrutiny, they have patterned many other "business" schemes in the same manner – laser, cryotherapy, brachytherapy, IMRT, and more. They came together in their double secret society, *The American Lithotripsy Society* (cleverly disguised as a lithotripsy education and "credentialing" organization), and with the booty heisted from healthcare consumers hired Tom Mills (the powerful DC attorney/lobbyist known for his lobbying efforts on behalf of Phillip Morris). The highly connected Mills and his firm, *Winston Strawn*, took advantage of hiring John McMickle away from his position as Senator Chuck Grassley's Chief of Staff. A very clear line to the Senate Finance Committee (Healthcare Subcommittee) was drawn and the talented Mr. Mills commanded the huge win by carving out that legislative *"Fair Market Value" Exception* within the *Anti-Kickback* law. *Voila!* But can anyone really ever define the term *"Fair Market Value?"* How clever and deceitful - therein lays the rub. So, brilliant as he is, Mr. Mills waved his magic wand, and has made it apparently lawful to get away with murder, as it were, as long as the "arrangements" are properly "structured." There is no justice in this for the American people. What happened here is frightening and grotesque and wrong and *illegal*. It is *RICO* on steroids.

It has become abundantly clear to me that so far no one of any authority to do something cares much about what has truthfully happened here to millions of people. The legislation for greed to trump medicine has been granted, and the millions of patients with no knowledge of how to fathom medical/legal subtleties are left entirely to fend for themselves. It is so wrong and so disgusting. It defies any human decency whatsoever.

What is the *"Fair Market Value"* of a kickback that corrupts sound medical judgment and conceals highly dangerous practices without disclosing risk? Can the FDA explain this?

It is germane to understand just how comprehensive and far their greed and the protection of this greed go. All the meetings are careful, small, private, clandestine, and spare, in hushed tones behind closed doors. Everyone is sworn to secrecy. These players gain their wealth by virtue of the volume of patients they treat and retreat with UESWL. They falsify medical research by means of lies of omission. They call it "protecting the evidence." They have their "highly trained technologists" totally hamstrung by paying them, as well, by the volume of patients that are treated. They have effectively made these technologists financially dependent on keeping their mouths shut about the improper use of the technology, whether it is by unnecessary or improper treatments or re-treatments. The urologists feel very confident by these "arrangements" that they are protected and that their medical judgment will never be questioned – there is code of silence that is comprehensively financially devised to conceal grave harm. And no one else of any authority is watching what is going on as the public has been duped and swindled in unspeakable ways.

It is my distinct understanding that our HHS OIG has historically been concerned that the amount of payment made to referring physicians is based on the volume of business generated by the referring physicians. The law has been designed now to teeter on the edge of just what that means, apparently. What about the kinds of commercially unreasonable payments that serve to corrupt medical judgment, show clear evidence of overutilization, and dramatically increase costs to taxpayers and Federal Healthcare programs, and vaporize competition? Have our government officials been "Jedi-mind-tricked?" Or is it just easier to turn a blind eye? What about when there is clear evidence of medical deception, harm, improper use, collusion, and unmistaken cooperation between competitive businesses to fix prices? What if properly "structured" "arrangements" are killing people, whether immediately or by damaging their health irreparably and causing premature death? What about all the lies...*all* the lies? What precisely is "improper" medical judgment, especially when there are clear choices and alternative treatments? In reality, does anything go – just how far do physicians get to ad-lib for kickbacks without oversight or accountability?

Anyway, you catch my drift. Thank you for your service.

Sincerely,

Anne Mitchell

Anne Mitchell
P.O. Box 3249
Oak Park, IL 60303
June 21, 2014

Via email (http://www.regulations.gov/)

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 30852

RE: Public Comment for Draft Guidance –
Devices Regulated by CDRH; Document #1833; Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval - Draft Guidance for Industry and Food and Drug Administration Staff

Dear Office of the Center Director:

Thank you for your dedicated commitment to the public health and safety of the American people, and for this opportunity to provide public comment concerning devices regulated by CDRH.

Respectfully, I hereby submit comment from personal experience as a healthcare professional having worked both in hospital-based academic clinical research and in the radiological device industry for many years. I am a whistleblower (*United States District Court Eastern District of Michigan 11-cv-10090*) and have filed a complaint with FDA (*CDRH CPT 1300384*).

With many years of exposure and involvement in different capacities to radiological devices in the marketplace, what I learned as an industry insider related to *Urinary Extracorporeal Shockwave Lithotripsy* was profoundly alarming. I learned not only that FDA post-market surveillance for this technology has been frighteningly deficient, but that the most likely reason for this is improper financial incentives devised to pay urologists for patient referrals to the procedure that are most often, if not entirely, *not* associated directly with the manufacturers of the devices. This scheme has permitted a separate and hidden layer of motivation for concealing serious adverse effects that might once have been deemed "rare" adverse events in the Pre-Market Approval phase performed in cooperation with device manufacturers, but could have easily and obviously been perceived and predicted to be substantial grave concerns over the mid-long term.

One of the most serious of these likely adverse UESWL events, though obvious, has never even been close on FDA's radar as a possible adverse event at all, and because of

the urologists' diabolical financial scheme has never been brought to the attention of the FDA by the urologists: the *significant increase in diabetes mellitus* in patients undergoing UESWL, the extent of which continues to remain widely unquantified in reality (Krambeck AE, et al. J Urol. 2006. May; 175(5): 1742-7). It appears that shockwaves may be damaging the fragile but critically functional islet cells within the pancreas, which due to anatomic proximity falls directly in the shockwave "blast path." A patient was actually killed in Michigan in October 2007 when the pancreas was essentially "exploded" by UESWL shockwaves. This event was never reported to FDA.

Serious concerns about renal damage and resulting functional renal deficiency, hypertension and its consequences, damage to spleen and stomach wall, and more, all that were well-warranted within Pre-Market Approval, were never followed to reasonable clinical resolution for demonstrating overall safety of the technology. Substantial financial incentives paid to urologists have stood in the way of exposing honest, transparent clinical information about critical functional aspects and the overall safety of UESWL in order to demonstrate its clear, fair, and objective position as a technology for the greater public health good now for thirty years. The cost of harm done is likely massive and incalculable.

Accessing clinical data, should FDA endeavor to assess it, from *Medicare* and *Medicaid* records will likely *not reveal* an adequate or realistic extent of the problem of diabetes mellitus as an adverse event (or for that matter any number of other adverse events) because American urologists *avoid* treating most *Medicare* and *Medicaid* patients with UESWL (Tan, HJ, et al. UROLOGY (2011) 78: 1287–1291.). They avoid these patients covered under government healthcare programs due to the constructs of their UESWL financial kickback schemes. Rest assured, however, the likelihood of *Medicaid* and *Medicare* paying for costly long-term adverse effects of UESWL in these same patients is extremely high. Take renal failure alone, for example, which costs *Medicare* nearly $33Billion annually – then consider diabetes: $174Billion annual *Medicare* dollars. From a government perspective, we are talking about *taxpayers and taxpayer dollars* all around.

After thirty years, due to urologists' distinct financial interests, medical research has been manipulated via obvious lies of omission in peer-reviewed medical literature about critically important safety and cost information concerning patients treated with UESWL. The likelihood as an alternative to UESWL that ureteroscopy damages the pancreas or spleen or stomach wall is effectively nil, for example. Urologists will likely never adequately voluntarily establish the difference between functional renal volumes following ureteroscopy versus UESWL because they are already quite certain what they will discover. These urologists are extremely smart people and they *do know* where the "bodies are buried." They are carefully, intentionally, methodically hiding what they know.

Though it is entirely possible today that millions of American people treated with UESWL are suffering adverse effects of functional renal volume loss that is compromising overall health and life quality, it is for no good clinical reason. The risk/benefit ratios for performing UESWL over obvious alternative treatments remain absolutely necessary but entirely publically unaddressed. Over time *all* the clinical lines have become blurred concerning patient selection for UESWL due to financial incentives. How many patients who might otherwise have undergone retrograde stone retrievals via ureteroscopy instead were treated and/or retreated with UESWL and are now gravely, inherently medically compromised by the functional loss of their treated kidney? This remains unknown for no good public health reason. These are patients who were conceivably already compromised by a metabolic dysfunction that first predisposed them to stone disease at all. This also remains unexamined in the risk/benefit profile. Data has not been correlated to reflect the incidence or prevalence of progression to hypertension and/or renal failure in these patients who've lost (or not lost) significant functional renal volume due to UESWL. These are serious adverse effects with incredibly high associated costs on many levels. And they are consciously, intentionally being hidden to protect the financial interests of a few.

What kind of choice is it, even were proper device labelling to be established, for a patient warning to state that use of UESWL may effectively destroy the functionality of the treated kidney, when that warning does not also require critical information about the risk/benefit ratio of UESWL by comparison to alternative treatments? The financially incented urologists may never even offer their patients alternative treatments to UESWL! Were patients to be informed of the medical implications, they perhaps may not want the functionality of their kidney to be risked, you think?

It is critically important for FDA to view today's landscape through a sobering and realistic lens by improving investigative knowledge in the Post-Market for where the "bodies are buried." This landscape is covered in thick weeds having been overrun with privately concealed improper financial incentives devised to compensate physicians for performing specific tests/procedures. It is entirely possible that information today concerning what may be necessary for establishing and preserving critical patient safety parameters through post-market surveillance may never be offered up through the traditional channels by the money-biased physicians themselves. The UESWL scheme is expansive enough that they have formed a massive "protective" front for themselves. This means that in order for FDA to fulfill its obligations to patient safety, the post-market surveillance process may be that much more difficult in today's corrupt climate. FDA may need to be carefully considering information about poorly conceived risks that may not have been given adequate consideration during Pre-Market Approval, which may prove to save many lives, as with the example of UESWL damage to the pancreas and disease progression to diabetes mellitus.

When determining a device is too unsafe to remain broadly on the market, or requiring far more honest and clinically precise labelling on devices with serious adverse effects,

never ever discount the scale of the powerful and dangerous influence of hidden schemes for financially incenting physicians beyond their human capacity for clinical objectivity.

As I have borne witness, thoughtfully and comprehensively considered programs requiring strong FDA post-market surveillance are crucial to keeping patients safe in today's multi-billion dollar "*shoot-first-aim-later- medical/financial-Wild-Wild-West*" heists. Thirty years is just far too long without critical surveillance of these deadly antics. Far too much harm at massive cost has been leveled, and far too many lives have been adversely affected.

Thank you for your consideration. Thank you for your service.

Sincerely,

Anne Mitchell
(708) 763-0501

Cc: Ms. Donna Engleman (CDRH)
Mr. Kevin Barry (DHHS OIG)

Anne Mitchell
PO Box 3249
Oak Park, IL 60303
July 29, 2014

Ms. Donna Engleman, BSN MS
Complaint Program Manager,
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Building 66, Room 2621
Silver Spring, MD 20993

RE: CDRH CPT1300384

Dear Ms. Engleman and the OC/FDA:

Thank you for your service. To reiterate my commitment to elucidating the facts about UESWL it is important to get down to the root. The manner in which "non-provider-physician owners" of UESWL services deceive the public comes at an outrageous cost to the American public. It is an unfair, deceptive, and fraudulent practice that mocks both health and care by focusing instead on the artificial marketplace they have manufactured for a technology whose safety record for serious adverse effects has intentionally remained hidden and unaddressed.

Urologists have manufactured self-serving, broad, and reckless discretion, selecting patients for UESWL not based on clinical judgment, but based on their potential for generating extraordinary profit. Protecting the very high prices they've set in the closed market they've created is made possible by fraudulently misrepresenting their practices to be "high quality" safe care when in fact they are instead dangerous, highly questionable care with unknown, even disproven safety records, and that by nature are intended to restrict innovation for real quality improvements. Extreme changes in referral patterns, dramatically increasing the numbers of patients treated and retreated becomes evident the moment urologists become "non-provider-physician-owners," with reckless disregard for the peril in which they place their patients. The harm is obvious.

Were one to have a tumor in one's knee or elbow, for example, which could either be removed to preserve the knee and leg, or elbow and arm, by a "tumor-ectomy" let's say, where the surgeon had ***no*** "non-provider-physician-ownership, or to be removed instead by means of the "non-provider-physician-ownership" of chainsaws leased at sky-high prices to facilities or hospitals for use in amputations, if this were to follow the UESWL scheme the number of amputations performed would rise dramatically. The excuse urologists use for UESWL is that patients "can survive with one kidney." The same could be said for the amputations – patients "can survive with one leg/arm." We could also substitute one's eye or ear in place of the leg/arm – a patient could "survive" with one eye or ear. What kind of medical judgment is that when the alternatives are obviously more safe and effective?

But here is where their whole line of reasoning goes down the toilet: The risk to one's survival for losing a single leg/arm/eye/ear at the hands of a money-grubbing doctor should they lose the opposing leg/arm/eye/ear in the future is a case of *morbidity* and not *mortality*. One could have no legs, arms, eyes, or ears and still "survive." One could not survive without kidneys – this is the big problem here. It is known to be a serious life-threatening disadvantage to have the function of only one kidney, especially when one is prone to kidney disease in the first place. This is the root of the problem here. It is not rocket science – it is obvious. The arguments they make through such public deception in order to profit from UESWL, risking lives of these patients without their informed consent in such a manner when it is unnecessary is an abomination given the facts of what we know to be true. It is unnecessary to place the vast majority's kidney function in such grave danger by using UESWL. There are obvious and much safer alternatives, but for the urologists' greed. Deceiving the public about the seriousness of this risk is a deadly crime.

Losing one's limbs, sight, or hearing would be devastating. But losing both kidneys *is* death. Having poor kidney function due to kidney damage substantially impacts life quality and overall health at substantial cost. When any one of these is lost it is debilitating, surely. But the risk is far greater for losing the other when at first one is lost. Profiting from this carefully crafted deception is the most outrageous demonstration of exploitation imaginable.

The recklessness deployed for the profit gained in what has been going on here now for thirty years by conforming American syndicated urologists, concealing clear knowledge and truthful disclosure of the dangerous facts concerning extent of the UESWL harm is truly unbelievable, and absolutely unforgiveable. That these lying, scheming charlatans have been able to pull the wool over the public's eyes given the distinct public expectation for ethical treatment in medicine is an extremely serious matter. Without clear, swift, and reasonable intervention for this severe breach of medical trust, the problem compounds itself with each passing day. As years pass, what will all this additional "collateral" damage be? Just what will the mortal cost of this process become?

The truth about this procedure has yet to be disclosed. Just how long will this take? These are important questions for your sincere consideration. Thank you.

Sincerely,

Anne Mitchell

Diabetes Mellitus and Hypertension Associated With Shock Wave Lithotripsy of Renal and Proximal Ureteral Stones at 19 Years of Followup

Amy E. Krambeck,* Matthew T. Gettman, Audrey L. Rohlinger, Christine M. Lohse, David E. Patterson† and Joseph W. Segura‡

From the Departments of Urology and Biostatistics (ALR, CML), Mayo Clinic College of Medicine, Rochester, Minnesota

Purpose: SWL has revolutionized the management of nephrolithiasis and it is a preferred treatment for uncomplicated renal and proximal ureteral calculi. Since its introduction in 1982, conflicting reports of early adverse effects have been published. However, to our knowledge the long-term medical effects associated with SWL are unknown. We evaluated these adverse medical effects associated with SWL for renal and proximal ureteral stones.

Materials and Methods: Chart review identified 630 patients treated with SWL at our institution in 1985. Questionnaires were sent to 578 patients who were alive in 2004. The response rate was 58.9%. Respondents were matched by age, sex and year of presentation to a cohort of patients with nephrolithiasis who were treated nonsurgically.

Results: At 19 years of followup hypertension was more prevalent in the SWL group (OR 1.47, 95% CI 1.03, 2.10, p = 0.034). The development of hypertension was related to bilateral treatment (p = 0.033). In the SWL group diabetes mellitus developed in 16.8% of patients. Patients treated with SWL were more likely to have diabetes mellitus than controls (OR 3.23, 95% CI 1.73 to 6.02, p <0.001). Multivariate analysis controlling for change in body mass index showed a persistent risk of diabetes mellitus in the SWL group (OR 3.75, 95% CI 1.56 to 9.02, p = 0.003). Diabetes mellitus was related to the number of administered shocks and treatment intensity (p = 0.005 and 0.007).

Conclusions: At 19 years of followup SWL for renal and proximal ureteral stones was associated with the development of hypertension and diabetes mellitus. The incidence of these conditions was significantly higher than in a cohort of conservatively treated patients with nephrolithiasis.

Key Words: kidney calculi, ureteral calculi, lithotripsy, diabetes mellitus, hypertension

In 1980 Chaussy et al introduced SWL with the HM-1 lithotriptor (Dornier Medical Systems, Marietta, Georgia) for renal stones.[1] After technological improvements the HM-3 was introduced to Europe for clinical practice in 1983. Based on this initial European experience the HM-3 lithotriptor was introduced in 1984 in the United States for symptomatic renal and proximal ureteral calculi.[2] This minimally invasive treatment revolutionized the management of urolithiasis and SWL flourished worldwide. In 2005 SWL was a preferred treatment in patients with renal calculi. In fact, indications for SWL have expanded, such that 80% to 90% of calculi can be treated successfully with SWL.[3]

The repetitive shock waves necessary for stone disintegration during SWL have been associated with early deleterious effects to the kidney and surrounding organs.[3–5] At intermediate followup (less than 5 years) the associations between SWL, and the development of hypertension and renal insufficiency are conflicting.[6] To our knowledge the long-term adverse medical effects related to SWL of the kidney and ureter are unknown. Using a posttreatment analysis with 19 years of followup we evaluated the long-term adverse medical effects associated with SWL.

MATERIALS AND METHODS

After approval from the Mayo Clinic Institutional Review Board a retrospective review identified 630 consecutive patients with renal and ureteral calculi who underwent SWL using an HM-3 lithotriptor in 1985. This year marked the first year of SWL at our institution. Appendix 1 lists the data collected. Preexisting renal insufficiency was defined as serum creatinine greater than 1.4 mg/dl in males and greater than 1.2 mg/dl in females. Preexisting obesity was defined as BMI 30 or greater. Preexisting hypertension was defined as a diagnosis of hypertension requiring antihypertensive medications. Stone analysis was performed on gravel passed via the urethra after treatment to determine composition. Hematuria with clot retention was considered a postoperative complication.

Selection of Cases

Of treated patients a structured questionnaire was sent to 578 listed in our clinic records as being alive in 2004. The questionnaire, which was developed and distributed with the Mayo Clinic Survey Research Center, focused on possi-

Submitted for publication June 23, 2005.
Study received Mayo Clinic Institutional Review Board approval.
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† Financial interest and/or other relationship with Olympus.
‡ Financial interest and/or other relationship with Boston Scientific.

TABLE 1. *Greater than 50% stone composition in all patients treated with SWL in 1985*

	No. Pts (%)
Calcium oxalate monohydrate	292 (43)
Calcium oxalate dihydrate	115 (16.9)
Calcium phosphate	123 (18.1)
Uric acid	28 (4.1)
Magnesium ammonium phosphate	17 (2.5)
Cystine	4 (0.6)
Unknown	72 (24.8)

ble adverse medical effects related to SWL for renal and ureteral calculi. A literature review was performed to identify acute adverse medical effects previously associated with SWL treatment. Based on the literature review and the visceral organs potentially in the SWL blast path a standardized inquiry regarding the development of multiple medical conditions was developed (Appendix 2). The change in BMI in this group was calculated from abstracted patient height and weight in 1985 and reported weight in 2004.

Selection of Controls

Controls were selected from patients diagnosed and followed at our institution in whom urolithiasis was managed nonsurgically. The control group was matched to the SWL questionnaire respondents on a 1:1 basis by age ± 5 years, sex and year of presentation ± 1 year. Medical records of the control group were retrospectively reviewed in the same manner as those of the cases. Data were collected regarding the development of disease conditions since 1985 (Appendix 2). The change in BMI was calculated from abstracted patient height and weight in 1985 and in 2004.

Statistical Analysis

Comparisons of age and sex between questionnaire responders and nonresponders were evaluated using the Wilcoxon rank sum and chi-square tests. Associations of SWL features with long-term outcomes were evaluated using the chi-square and 2-sample t test. Conditional logistic regression models were used to evaluate the risk of long-term outcomes associated with SWL. The risk of these outcomes were evaluated univariately and in a multivariate setting, adjusting for BMI as assessed in 2004 and the change in BMI from 1985 to 2004. Statistical analyses were performed using the SAS software package (SAS Institute, Cary, North Carolina) with $p < 0.05$ considered statistically significant.

RESULTS

Retrospective Review of All Patients With SWL

Retrospective chart review revealed a total of 687 SWL treatments in 630 patients from January 1, 1985 to December 31, 1985. Eight patients were excluded due to age in 7 and refusal to authorize research in 1. Median patient age was 52 years (range 18 to 90). There were 218 females and 404 males. Stone location was on the left side in 384 cases, on the right side in 295 and bilateral in 57. There were 541 solitary renal stones, 27 multiple renal stones and 114 proximal ureteral stones. According to available stone sizes 34.9% of the stones were less than 1 cm, 58.4% were 1 cm or greater and 6.6% were partial staghorn calculi. Table 1 shows stone composition.

TABLE 2. *Questionnaire respondent demographics*

	No. Pts (%)
Overall	288
Sex:	
M	182 (63.2)
F	106 (36.8)
Preop obesity (BMI 30 or greater):	
Yes	74 (25.7)
No	212 (73.6)
Unknown	2 (0.7)
Preop renal insufficiency	16 (5.6)
Preop Hypertension	28 (9.7)
Preop DM	8 (2.8)
Stone side:	
Lt	151 (52.4)
Rt	137 (47.6)
Multiple sides:	
Yes	26 (9.0)
No	262 (91.0)
Location:	
Renal	236 (81.9)
Ureteral	52 (18.1)
Multiple	9 (3.1)
Single	279 (96.9)

Median patient age at SWL was 48.5 years (range 16 to 79).

Comparison of Questionnaire Responders and Nonresponders

Of the 578 questionnaires mailed 89 were not completed because the patient was deceased. The completed survey response rate of contacted patients was 58.9%. There were no significant differences in age and sex between the 288 responders and 201 nonresponders. Of the questionnaire responders 228 (81.4%) had been referred for SWL and did not return for followup to our clinic postoperatively.

Questionnaire Respondents

Table 2 lists demographics, comorbidities and stone locations in respondents. Preexisting hypertension was noted in 28 cases (9.7%), preexisting renal insufficiency was noted in 16 (5.6%), preexisting DM was noted in 8 (2.8%) and preexisting obesity was noted in 74 (25.7%). Median patient weight at treatment was 79.0 kg (range 42 to 134.5). Stone location in this group was renal in 236 (81.9%) and proximal ureteral in 52 (18.1%). Table 3 lists the characteristics of SWL in respondents. Overall 3 patients received greater than 2,000 shocks at a single setting and 10 received greater than 2,000 shocks as a cumulative amount during multiple SWLs.

An immediate postoperative complication was noted in 40 of the 288 responders (13.9%) (table 4). While routine postoperative computerized tomography or ultrasound was not performed, no clinically significant perinephric hematomas

TABLE 3. *SWL interventions in questionnaire respondents*

Treatments	No. Pts	Median (range)
No. SWL treatments:		
1	270 (93.8%)	
1–3	18 (6.2%)	
Av voltage (kV)	288	20 (19–24)
No. shocks	288	1,100 (300–4,500)
Av intensity*	288	22,000 (5,700–55,200)
Total intensity	288	24,000 (5,700–93,600)

* Patients receiving more than 1 SWL treatment had an average intensity based on the average of their total treatments.

TABLE 4. *Immediate postoperative complications*

Postop Complications	No. Pts (%)
Pain	8 (2.8)
Ureteral edema/obstruction	7 (2.4)
Sepsis	6 (2.1)
Steinstrasse	6 (2.1)
Chest pain	3 (1.1)
Myocardial infarction	3 (1.1)
Fever	2 (0.7)
Hematuria + clot retention	2 (0.7)
Abscess	1 (0.4)
Arrhythmia	1 (0.4)
Deep venous thrombosis	1 (0.4)
Hypotension	1 (0.4)
Ureteral perforation	1 (0.4)

No patient had diarrhea, increased liver function tests, ileus, perinephric hematoma, pneumonia, renal failure or stroke.

were noted. Certain patient characteristics were associated with immediate postoperative complications. Patients with preoperative renal insufficiency were at increased risk for an immediate complication ($p < 0.001$). As patient age increased, the risk of any immediate complication increased ($p = 0.002$). The development of any complication was associated with the number of shocks ($p < 0.001$), voltage in kV ($p = 0.012$), average intensity ($p < 0.001$), total intensity ($p < 0.001$), number of locations treated ($p = 0.013$) and number of separate SWL treatments ($p = 0.015$). There was no association between immediate complications and preoperative obesity.

Table 5 lists statistically insignificant conditions in the SWL group after 19 years of followup. New onset hypertension was noted in 103 cases (36.4%). Renal insufficiency since the date of SWL was noted in 14 cases (5.2%). New onset DM was noted in 48 patients (16.8%), of whom 12.5% were insulin dependent. Obesity was noted in 64 patients (29.6%). Median patient weight at followup was 80.9 kg (range 49.2 to 137).

Controls

Of the 288 controls stone location was on the left side in 148, on the right side in 127, renal in 232 and ureteral in 54. Average stone size was 0.45 cm (range 0.1 to 2.0) and 205 stones passed spontaneously. Obesity was noted in 100 controls (35.3%) at stone diagnosis. Median patient weight at presentation was 82.2 kg (range 51.0 to 145.7). Preexisting hypertension was noted in 48 patients (16.7%), preexisting renal insufficiency was noted in 5 (1.7%) and preexisting DM was noted in 0 (3.1%) at stone diagnosis in 1985.

At 19 years of followup 44.0% of controls had renal calculi. New onset hypertension and renal insufficiency were identified in 79 (27.4%) and 23 patients (8.0%), respectively, while newly diagnosed DM was noted in 19 (6.6%). Obesity was observed in 54 controls (18.9%). Median patient weight was 78.0 kg (range 45.0 to 135.0) in 2004.

Case-control Comparison of Disease Prevalence

The development of DM was significantly different between SWL treated patients and controls. Patients treated with SWL were more likely to have new onset, medically treated DM at 19 years of followup (OR 3.23, 95% CI 1.73 to 6.02, $p < 0.001$). There was a difference between the number of obese patients in the SWL and control groups at 19 years of followup with more obese individuals in the SWL group (64 vs 42, OR 1.76, 95% CI 1.12 to 2.77, $p = 0.015$). There was a significant change in BMI between the 2 groups with patients losing weight in the control group compared to those in the SWL group with a median change in BMI in the control and SWL groups of −1.99 and 0.86, respectively ($p < 0.001$). Multivariate analysis controlling for obesity in 2004 revealed a persistent significant risk of DM after SWL compared to that in controls (OR 3.28, 95% CI 1.49 to 7.24, $p = 0.003$). Controlling for the change in BMI again showed a persistent risk of DM in the SWL group (OR 3.75, 95% CI 1.56 to 9.02, $p < 0.003$). New onset DM was related to the total number of shocks delivered and average intensity ($p = 0.005$ and 0.028, respectively). Stone location and side of treatment were not associated with DM (table 6).

Case-control comparison demonstrated a significant difference in the development of hypertension between the SWL and control groups with the SWL group more likely to have hypertension (OR 1.47, 95% CI 1.03 to 2.10, $p = 0.034$). New onset hypertension was not related to the total number of shocks ($p = 0.620$), average intensity ($p = 0.464$) or total intensity ($p = 0.693$). However, bilateral SWL was associated with hypertension ($p = 0.033$). Table 7 shows the complete analysis of hypertension and renal insufficiency. There was no statistically significant difference in the development of renal insufficiency between cases and controls. Table 8 shows a case-control comparison of disease processes.

DISCUSSION

In 1984 the HM-3 lithotriptor was introduced to the United States.[7] This treatment modality became widely accepted based on its safety and noninvasiveness. Much has been learned about postoperative complications since the HM-3 was introduced. It is now recognized that shock waves can cause acute damage.

Strong evidence has developed that implicates SWL as a cause of transient acute renal damage and damage to surrounding tissues. Hypertension following SWL has been an ongoing controversy since the original reports of acute onset hypertension following SWL were published in the mid to late 1980s.[8,9] However, subsequent studies with intermediate followup (less than 5 years) did not demonstrate these effects on blood pressure.[10,11] Immediate damage to the kidney or adjacent organs occurs infrequently following SWL,[12] and yet major injuries to the kidney and all adjacent organs have been

TABLE 5. *Statistically significant conditions in SWL group at 19-year survey followup*

Condition	% Respondents
Hematuria	33.5
Cystitis/urinary tract infection	29.1
Current stone	28.2
Proteinuria	18.7
Pyelonephritis	9.6
Renal cystic disease	3.4
Colon Ca	2.5
Pancreatitis	1.8
Pancreatic Ca	1.8
Adrenal insufficiency	1.5
Liver dysfunction/failure	1.4
Adrenal tumor	1.1
Kidney tumor	0.7
Hepatic tumor	0.4

TABLE 6. *Patient and SWL characteristics related to DM at 19-year followup*

No. Pts	DM 48	No DM 237	p Value
Median age at SWL (range)	48 (18–65)	48 (16–79)	0.804
No. sex (%):			
F	13 (12.3)	93 (87.7)	0.112
M	35 (19.5)	144 (80.5)	
No. obese (%):			
No	24 (11.4)	187 (88.6)	<0.001
Yes	23 (31.9)	49 (68.1)	
No. stone side (%):			
Lt	23 (15.3)	127 (84.7)	0.473
Rt	25 (18.5)	110 (81.5)	
No. location (%):			
Renal	38 (16.2)	196 (83.8)	0.560
Ureteral	10 (19.6)	41 (80.4)	
No. bilat SWL (%):			
No	47 (18.1)	212 (81.9)	0.094
Yes	1 (3.8)	25 (96.2)	
No. pts (%):			
1 SWL	43 (16.1)	224 (83.9)	0.199
Greater than 1 SWL	5 (27.8)	13 (72.2)	
Median No. shocks (range)	1,300 (500–4,500)	1,100 (300–3,700)	0.005
Median av kV voltage (range)	20 (19–24)	20 (19–24)	0.658
Median av intensity (range)	26,200 (11,000–5,200)	22,000 (57,000–48,000)	0.028
Median total intensity (range)	27,200 (11,000–93,600)	22,000 (5,700–88,800)	0.007

reported.[7] To our knowledge the long-term adverse medical effects associated with SWL are unknown to date.

In this study we found that hypertension and DM were associated with SWL at 19 years of followup. To our knowledge this is the longest followup of patients treated with SWL and the only study to demonstrate an association between SWL and DM. We found a significant association between the development of DM in patients treated with SWL compared to that in conservatively treated patients with stones. A significant risk of DM in the SWL group was present after controlling for differences in obesity and the change in BMI in the 2 groups on multivariate statistical analysis. DM was related to the number of shocks administered at SWL and the intensity of SWL treatment. Hypertension was also significantly higher in patients in the SWL treatment group. Furthermore, the risk of hypertension was higher in patients undergoing bilateral SWL treatments.

DM in our SWL group could be a result of damage to pancreatic islet cells. The pancreas is in the blast path of the HM-3 regardless of the side of treatment. It is known SWL for renal calculi affects pancreatic tissue without overt pancreatitis since increases in serum and urinary amylase, and serum lipase have been noted.[13] Case reports of acute pancreatitis after SWL have also been published.[14,15] Microvascular damage to the pancreas and small hematomas have been demonstrated after SWL with advanced imaging modalities.[16] It is postulated that the cavitation and shear forces produced by shock waves passing through tissue in-

TABLE 7. *Patient demographics and SWL treatments related to hypertension and renal insufficiency at 19-year followup*

	Hypertension			Renal Insufficiency		
	Yes	No	p Value	Yes	No	p Value
No. pts	103	180		14	255	
Median age at SWL (range)	48 (16–71)	48 (16–79)	0.888	50.5 (18–59)	48 (16–79)	0.756
No. sex (%):						
F	35 (33.3)	70 (66.7)	0.411	6 (6.1)	92 (93.9)	0.608
M	68 (38.2)	110 (61.8)		8 (4.7)	163 (95.3)	
No. obese (%):						
No	70 (33.5)	139 (66.5)	0.096	8 (4.0)	192 (96.0)	0.323
Yes	32 (44.4)	40 (55.6)		5 (7.4)	62 (92.6)	
No. preop renal insufficiency (%):						
No	89 (36.2)	157 (63.8)	0.845	12 (5.2)	220 (94.8)	1.000
Yes	14 (37.8)	23 (62.2)		2 (5.4)	35 (94.6)	
No. stone side (%):						
Lt	54 (36.5)	94 (63.5)	0.974	10 (7.1)	131 (92.9)	0.144
Rt	49 (36.3)	86 (63.7)		4 (3.1)	124 (96.9)	
No. location (%):						
Renal	83 (35.9)	148 (64.1)	0.732	13 (5.9)	207 (94.1)	0.477
Ureteral	20 (38.5)	32 (61.5)		1 (2.0)	48 (98.0)	
No. bilat SWL (%):						
No	89 (34.5)	169 (65.5)	0.033	13 (5.3)	230 (94.7)	1.000
Yes	14 (56.0)	11 (44.0)		1 (3.8)	25 (96.2)	
No. pts (%):						
1 SWL	100 (37.6)	166 (62.4)	0.098	14 (5.6)	237 (94.4)	0.608
Greater than 1 SWL	3 (17.6)	14 (82.4)		0	18 (100.0)	
Median No. shocks (range)	1,125 (500–4,500)	1,100 (300–3,900)	0.620	1,200 (600–2,000)	1,100 (300–4,500)	0.365
Median av kV voltage (range)	21 (19–24)	20 (19–24)	0.806	20 (20–24)	21 (19–24)	0.203
Median av intensity (range)	24,000 (10,000–55,200)	22,000 (57,000–48,000)	0.464	24,100 (12,000–48,000)	24,000 (5,700–93,600)	0.236
Median total intensity (range)	24,000 (10,000–93,200)	24,000 (5,700–93,600)	0.693	24,100 (12,000–48,000)	24,000 (5,700–93,600)	0.445

TABLE 8. *DM, renal insufficiency and hypertension in SWL and control groups*

Conditions	No. SWL (%)	No. Control (%)	OR (95% CI)	p Value
Renal insufficiency	14 (5.2)	23 (8.6)	0.59 (0.3–1.17)	0.133
Hypertension	103 (36.4)	79 (27.9)	1.47 (1.03–2.10)	0.034
DM	48 (16.8)	19 (6.7)	3.23 (1.73–6.2)	0.001
DM controlling for BMI			3.28 (1.49–7.24)	0.003
DM controlling for BMI change			3.75 (1.56–9.02)	0.003

duces cell damage. This is considered the underlying cause of injury to adjacent organs, including the pancreas, after SWL.[15] The severity of soft tissue damage is related to the total number of shock waves and the frequency delivered.[13] This collateral damage may be worse with the HM-3 because it has the greatest focal area of 15 × 127 mm (width × height) compared to subsequently developed lithotriptors.[17]

Damage to the pancreas could further increase the risk of DM in patients with predisposing risk factors such as obesity. Preoperatively obese patients treated with SWL were more likely to have DM after SWL than nonobese patients treated with SWL. The development of DM following SWL was independent of BMI on multivariate statistical analysis, supporting the theory of pancreatic cell damage potentiating DM in patients with predisposing risk factors. However, further studies would be required in support of this theory.

We also noted a significant risk of hypertension after SWL. Large population based studies have demonstrated a correlation between hypertension and stone formation.[18] The rate of treated hypertension in this study is high in the SWL and control groups compared to quoted rates in the general population (46.3% and 44.1%, respectively, vs 25%).[19] However, after excluding patients with preexisting hypertension in the 19-year period the development of hypertension was significantly higher in the SWL group. Renal parenchymal or vascular changes related to SWL could contribute to hypertension in the SWL group. This effect may be exacerbated by bilateral SWL treatments.

We recognize limitations of this study. Patients who died before 2004 were not studied and, therefore, adverse long-term outcomes in these patients are not available. The response rate to the survey is altered by the proportion of deceased patients. Only 18.6% of the patients were followed at our clinic. Therefore, the 60% response rate may be falsely low due to surveys sent to unrecognized deceased patients. Lastly, long-term outcome data on patients with SWL were obtained by a questionnaire. Outcome data on controls were collected by retrospective chart review of patients followed at our clinic. This could have introduced collection bias in the results. Our institution obtained the HM-3 soon after its introduction to the United States, giving us the unique opportunity to perform long-term followup. Nonetheless, the mentioned limitations are in part the result of being a major referral center for SWL when its initial access was limited.

This study was based on the HM-3 lithotriptor, which is still considered the gold standard for SWL. Subsequent generations of lithotriptors have failed to demonstrate comparable stone-free rates. The HM-3 is unique in its large focal zone, which may contribute to the deleterious effects associated with SWL. Further studies with other lithotriptors should be performed to determine their respective long-term adverse medical effects since, although newer models have smaller focal zones, they generate greater pressures at F2, which is associated with tissue trauma. Furthermore, these adverse effects should be brought to light as newer lithotriptors are developed that attempt to reproduce the success of the original HM-3.

CONCLUSIONS

In this case-control study treating renal and proximal ureteral calculi with the HM-3 lithotriptor was associated with DM and hypertension at 19 years of followup. DM was related to the number of shocks administered and the total intensity of SWL treatment. Hypertension strongly correlated with bilateral SWL treatment.

APPENDIX 1

Data on All Patients Collected by Retrospective Chart Review

PREOPERATIVE PATIENT CHARACTERISTICS

Age
Gender
BMI
Preexisting medical conditions
Stone location
Stone size
Stone composition

OPERATIVE DATA

Number of SWL procedures
Total number of shocks administered
Voltage (kV)
Total intensity (number of shocks × voltage across SWL treatments)
Average intensity of multiple treatments per patient
Side of treatment
Immediate postoperative complications (those occurring within 48 hours of SWL)

APPENDIX 2

Disease Processes Covered in Case Survey

Renal insufficiency
Renal tumors
Renal cystic disease
Hypertension
DM
Pancreatitis
Pancreatic cancer
Hepatic dysfunction
Hepatic tumors
Colon cancer
Adrenal insufficiency
Adrenal tumors

Definition for the following diseases differ from preoperative definitions as information was obtained from survey.

Renal insufficiency was defined as renal impairment or renal failure diagnosed by a physician.

Hypertension was defined as elevated blood pressure requiring antihypertensives prescribed by a physician.

DM was defined as a diagnosis of DM by a physician and requiring therapeutic intervention.

Abbreviations and Acronyms

BMI = body mass index
DM = diabetes mellitus
SWL = shock wave lithotripsy

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Kidney stones are solid concretions of minerals and other substances that form in the kidney. Such stones may travel from the kidney to the ureter, a process that frequently results in severe pain. They may also grow to a large size and obstruct the kidney, which may cause permanent damage and renal insufficiency.[1] In addition, stone formation may result in end stage renal disease, particularly in patients with primary hyperoxaluria who are at highest risk.[2] A small number of individuals, fewer than 1 percent, may die of complications (such as sepsis) associated with kidney stones. Genetic factors play a role in kidney stone formation in the majority of patients.

A small number of individuals develop stones due to monogenic disorders such as cystinuria, the primary hyperoxalurias, chloride channel disorders, hypoxanthine-guanine phosphoribosyl transferase deficiency and adenine phosphoribosyl transferase deficiency. The responsible genes for these entities have been well characterized. However, the majority of stone formers have idiopathic calcium oxalate nephrolithiasis. This is a polygenic disorder and the responsible genes have not yet been identified.[3]

Kidney stone formation should be considered a systemic disease due to its association with many other disease processes, including diabetes mellitus, hypertension, obesity, certain gastrointestinal disorders, renal tubular acidosis, gout, primary hyperparathyroidism and bone disease. There are also strong associations with nutrition.[4] While effective non-invasive treatments for eradicating stones, such as shock wave lithotripsy (SWL), have been developed, there are potential downstream complications of this procedure, such as diabetes mellitus and hypertension.[5]

The prevalence of kidney stones in the United States is increasing and is estimated to be 5 percent greater than the last decade.[6] Kidney stones most commonly develop in white males during the third to sixth decades of life, although infants and geriatric patients may also form stones. The male/female ratio for the development of kidney stones has changed from 1.7:1 to 1.3:1, perhaps due to environmental stresses.[7] Nephrolithiasis exerts significant economic stress on the United States, as the estimated cost of providing care for individuals of working age with kidney stones in this country was $5.3 billion dollars (direct and indirect costs) in 2000.[8]

There are advances that need to be made in stone basic science research, including integration of physical chemistry (crystal generation and retention), anatomical changes (Randall's plaque and other histological changes) and physiological responses.[9] Factors that regulate urinary excretion of calcium, oxalate and citrate, major metabolic risk factors for stone formation, as well as the properties of inhibitors of crystallization and their participation in these processes need to be further defined, including at a molecular level.[10]

Identifying susceptibility genes is paramount, as this should facilitate a better understanding of the aforementioned events and the development of more targeted preventive medical therapy. The role that certain colonic bacteria play such as Oxalobacter formigenes in calcium oxalate kidney stone prevention needs to be determined.[11] Research on cystinuria should be a priority, as this is the most common of the monogenic stone forming disorders. These patients tend to form stones earlier in life, are prone to recurrence and may have renal damage.[12]

Struvite stones, which form in some individuals whose urinary tract is infected with urease-producing organisms, can reduce renal function and lead to death. Yet not all such infections lead to struvite stone formation, and investigation of the interactions of the urothelium, infecting organisms and collecting system dynamics that differentiate these outcomes may lead to strategies to prevent this condition.

A better understanding of the physiology and dynamics of the collecting system could lead to pharmacologic prevention or relief of ureteral obstruction due to spasm or edema, which would promote spontaneous passage of stones as well as improve the passage of fragments after lithotripsy or ureteroscopic fragmentation.

Epidemiological research is required to better define the scope and extent of this problem (incidence, prevalence, recurrence), populations at risk, associated comorbidities and economic impact. This will, in turn, facilitate the design of clinical trials and comparative effectiveness studies to determine the optimal methods for diagnosis, stone removal and prevention, as well as compare outcomes of SWL and ureteroscopy. An SWL registry should be supported to help determine the subsequent risk of developing systemic diseases, such as diabetes mellitus and hypertension, and associated risk factors.

There must be increased attention to pediatric stone disease and the long-term sequelae it produces. It is important to develop optimal metabolic evaluation and medical treatment regimens for children, as well as guidelines on how best to treat children with stones, from a surgical as well as a medical and metabolic standpoint. It is time to evaluate drug regimens similar to those applied to the adult population for potential use in the pediatric population.

Utilization of new technologies will advance stone research. Proteomics will help identify proteins associated with stone formation in stones, urine and tissues. Genome-wide association studies will permit the identification of susceptibility genes and can also be linked to proteomics.

These novel technologies should permit a better understanding of the association of kidney stone formation with a number of associated diseases. Genetic data will permit the development of animal models to better approximate the disease process in humans and facilitate studies of pathophysiology, as well as the development of preventive and therapeutic strategies.

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Collaboration with members of the UTI research community will accelerate identification of common mechanisms that will permit advances in the management of patients with struvite stones. Such collaborations may provide more insight into the fecal microbiome and its influence on stone formation or prevention.

Patients with the metabolic syndrome are at risk for the development of kidney stones as well as a number of other urological disorders including erectile dysfunction, benign prostatic hyperplasia and lower urinary tract symptoms, incontinence, infertility and prostate cancer.[13] Common mechanisms may be involved in these processes providing an avenue for synergistic research.

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Understanding Financial Conflicts of Interest

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The problem of conflicts of interest began to receive serious attention in the medical literature in the 1980s[1-3]. Studies have described a wide range of conflicts involving physicians, medical researchers, and medical institutions (the most comprehensive is by Rodwin[3]). Among the areas of concern are self-referral by physicians,[4,5,6] physicians' risk sharing in health maintenance organizations (HMOs) and hospitals,[7] gifts from drug companies to physicians,[8,9] hospital purchasing and bonding practices,[3] industry-sponsored research,[10,11] and research on patients[12]. Yet the concept of conflict of interest itself has been inadequately analyzed, and consequently its elements, the purposes of regulation, and standards for assessment are still often misunderstood.

Elements of Conflicts of Interest

A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).

[Interessenkonflikt bezeichnet eine Reihe von Zuständen, unter denen professionelles Urteil, dass sich auf ein primäres Interesse bezieht (wie z.B. das Wohl des Patienten oder die Validität von Forschung) dazu tendiert, unangemessen beeinflusst zu werden durch ein sekundäres Interesse (z.B. finanzieller Vorteil) (Übersetzung D.K.)]

The **primary interest** is determined by **the professional duties** of a physician, scholar, or teacher. Although what these duties are may sometimes be controversial (and the duties themselves may conflict), there is normally agreement that whatever they are, they should be the primary consideration in any professional decision that a physician, scholar, or teacher makes. In their most general form, the primary interests are the health of patients, the integrity of research, and the education of students.

The secondary interest is usually not illegitimate in itself, and indeed it may even be a necessary and desirable part of professional practice. Only its relative weight in professional decisions is problematic. The aim is not to eliminate or necessarily to reduce financial gain or other secondary interests (such as preference for family and friends or the desire for prestige and power). It is rather to prevent these secondary factors from dominating or appearing to dominate the relevant primary interest in the making of professional decisions.

Conflict-of-interest rules usually focus on financial gain, not because it is more pernicious than other secondary interests but because it is more objective and more fungible. Money is easier to regulate by impartial rules, and it is also generally useful for more purposes. It is therefore a mistake to object to the constraints on financial gain by complaining that there are other kinds of influence (e.g., "an interest in obtaining provocative results" or pressure to favor "previously published findings of colleagues, friends, or researchers in collaborating groups"[13,14]) that can have equally bad or worse effects on professional judgment. Just because we cannot do much about the other secondary interests, it does not follow that we should do little about financial gain. (This point also applies to types of financial interests; we might choose to proscribe one type, but not another[15].)

It is also a mistake to treat conflicts of interest as just another kind of choice between competing values, as occurs with ethical dilemmas involving termination of care, confidentiality, or the use of human subjects in research. To do so dilutes the concept of a conflict of interest and encourages the attitude that conflicts are so pervasive that they cannot be avoided. In ethical dilemmas, both of the

competing interests have a presumptive claim to priority, and the problem is in deciding which to choose. In the case of financial conflicts of interest, only one of the interests has a claim to priority, and the problem is to ensure that the other interest does not dominate. This asymmetry between interests is a distinctive characteristic of conflicts of interest.

Reasons for Regulating Conflicts of Interest

A common criticism of rules governing conflicts of interest is that they unfairly punish ethical physicians and researchers for the misdeeds of the few unethical ones. Rules regulating conflicts in research are said to be a "serious insult to the integrity of scientists" who have any financial connection with industry[13]. "To ascribe a conflict of interest automatically in such situations amounts to an assumption that the sponsor's interests have influenced the investigator . . . and that the research findings are different from what they would otherwise have been"[13].

Similarly, rules regulating self-referral are said to assume falsely that physicians prescribe drugs or order diagnostic tests in which they have a financial interest without regard to whether the drugs or tests are in the patient's interest[16]. Critics argue that, on the contrary, patients benefit in the long run because a physician's financial interest in the facility to which he or she refers patients creates a strong incentive to ensure that it provides high-quality care[15,17].

Criticisms of this kind rest on a mistaken view of the basic purposes of conflict-of-interest rules. The first purpose is to maintain the integrity of professional judgment. The rules seek to minimize the influence of secondary interests (such as personal financial gain) that should be irrelevant to the merits of decisions about primary interests (such as the care of a patient or the conduct of research). The rules do not assume that most physicians or researchers let financial gain influence their judgment. They assume only that it is often difficult if not impossible to distinguish cases in which financial gain does have improper influence from those in which it does not. It is difficult even in one's own case, and all the more so in the case of people one does not know personally, to determine what motives have influenced a professional decision. Given this general difficulty of discovering real motives, it is safer and therefore ethically more responsible to decide in advance to remove insofar as possible factors that tend to distract us from concentrating on medical and scholarly goals.

Why not simply judge professional decisions by their results? One reason is that many treatment or referral decisions are never reviewed by anyone other than the physicians directly involved. Neither is the market an adequate test of results; it provides only limited protection against the harmful effects of conflicts of interest[15]. In the conduct of research, peer review of results offers greater protection. But the objectivity of a particular piece of research is not the only concern, as many commentators suppose it is[13]. The more far-reaching issue, which peer review does not normally address, is the choice of topics and the direction of research -- for example, the tendency of industry-sponsored researchers to put more emphasis on commercially useful research than basic research[18]. Nor do conflict-of-interest rules encourage one to "focus attention on the circumstances of the writer rather than on the substance of the writing and thereby stifle objectivity"[14]. There is no reason that one cannot consider both the circumstances and the substance. Furthermore, the point of the rules is to eliminate or reduce certain kinds of circumstances so that the scholar can concentrate on substance.

The second purpose of conflict-of-interest rules depends even less on the assumption that physicians neglect patients or researchers produce biased results because of the influence of financial gain. That purpose is to maintain confidence in professional judgment. The aim is to minimize conditions that would cause reasonable persons (patients, colleagues, and citizens) to believe that professional judgment has been improperly influenced, whether or not it has.

Maintaining confidence in professional judgment is partly a matter of prudence. To the extent that the public and their representatives distrust the profession, they are likely to demand greater regulation of practice and research and are likely to supply fewer resources for both. Patients may be less likely to trust physicians generally. Since the actions of individual physicians and researchers can affect public confidence in the whole profession,[19] individual professionals have an obligation, both to the public and to the profession, to make sure that their own conduct does not impair their colleagues' capacity to practice medicine or conduct research.

A failure to avoid a conflict of interest may therefore be wrong even when one is not influenced by secondary interests at all. When professionals do not take reasonable precautions to **avoid situations of conflict** or do not observe rules regulating such conflicts, they have acted unethically. Contrary to the view of some commentators,[14] a charge of a conflict of interest may indeed constitute an accusation, even in the absence of an otherwise improper motivation.

Standards for Assessing Conflicts of Interest

Standards for assessing conflicts of interest identify factors that make conflicts more or less problematic. The severity of a conflict depends on (1) the likelihood that professional judgment will be influenced, or appear to be influenced, by the secondary interest, and (2) the seriousness of the harm or wrong that is likely to result from such influence or its appearance.

In assessing likelihood, we may reasonably assume that, within a certain range, **the greater the value of the secondary interest (e.g., the size of the financial gain), the more probable its influence. Below a certain value, the gain is likely to have no effect; this is why de minimis standards (which define that value) are appropriate for some gifts.** Also, the value should generally be measured in relation to typical income and to the scale of the practice or research project.

Also affecting likelihood is the scope of conflict, in particular the nature of the relationship that generates the conflict. Longer and closer associations increase the problem. A continuing relationship as a member of the board or a limited partner of an industrial sponsor, for example, creates a more serious problem than the acceptance of a one-time grant or gift.

The extent of discretion -- that is, how much latitude a physician or researcher enjoys in exercising professional judgment -- partly determines the range of probabilities. The more routine the treatment or the more closely it follows conventional professional practice, the less room there is for judgment and hence for improper influence. Also, the less independent authority the professional has in a particular case, the less latitude there is for improper influence. A conflict involving a laboratory technician, for example, is generally less severe than one involving a principal investigator.

In assessing the seriousness of a conflict, we consider first the value of the primary interest -- the effects on a patient's welfare or the effects on the integrity of the research. These effects include not only the possibility of direct harm to the patient or the research, but also the indirect harm that results from a loss of confidence in the judgment of the physician or researcher.

The greater the scope of the consequences, the more serious the conflict. Beyond its effects on the particular patient or research project, a conflict may have effects on the practices of other physicians or on the research projects of colleagues. Questions such as these should be considered: Will this physician's association with a commercial laboratory raise doubts about the objectivity of all the physicians in his or her hospital or HMO? Will the fact that this drug company is sponsoring this research project tend to undermine confidence in the results of the work of other scholars in the institution and their ability to raise funds from other sources? Claims of physicians' independence or academic freedom should not be allowed to obscure the fact that the actions of any particular physician or scholar may substantially affect the independence of colleagues.

Finally, the more limited the accountability of the physician or researcher, the more serious the conflict. If the decision of a physician is reviewable by colleagues or authorities (who do not themselves have conflicts of interest), then there is less cause for concern. But the reviewers must be, and must be seen to be, genuinely independent and effective. Even if professionals are accountable for particular decisions, however, they may escape scrutiny for the cumulative effects and broader policy implications of their decisions. The informal norms and policies of a hospital or HMO represent judgments that, no less than explicit decisions in particular cases, may be improperly influenced by secondary interests.

Remedies

Historically, the trend has been from less to more extensive control of conflicts of interest -- from individual discretion to collective regulation. The more severe the conflicts, the more justifiable are more extensive forms of control.

Relying on the good character of individual physicians and scholars to ensure that they avoid conflicts, or deal with them judiciously when they arise, is the least intrusive procedure. It also has the advantage of maintaining conditions of mutual trust between physicians and patients and between scholars and their public. It is, however, more effective in face-to-face relations that continue over time -- in small communities, for example, in which patients know their physicians personally. It is less likely to be adequate in large organizations and in the impersonal encounters or distant relationships that characterize much of the practice of modern medicine and medical research.

Regulation by the profession provides more assurance than individual discretion that conflicts will be avoided. As compared with government regulation, it also has the advantage of involving those who know and care personally about professional practice. Rules are more likely to fit the special circumstances of the clinic and the laboratory when they are written by those who know these circumstances well and who have a personal stake in maintaining the integrity of the profession. The disadvantage of relying exclusively on the profession is that physicians, not only individually but also collectively, confront a conflict between their primary interest in maintaining the integrity of the profession and their secondary interest in promoting the economic welfare of its members. **Unlike many other professions, the medical profession did not formally address conflicts of interest in its codes until the 1980s, and even then it in effect left the problem to the discretion of individual physicians[3]. Only in 1991 did the American Medical Association declare that self-referral, for example, was "presumptively inconsistent" with a physician's obligation to patients[6].**

The growing role of governments in regulating conflicts of interest is in part a response to the failure of physicians and scholars to deal adequately with the problem and in part a result of the greater stake that society has in medical practice and research. Despite the claim of some physicians that ethics cannot be legislated,[20] law and morality overlap and interact in many ways, most of which are mutually reinforcing. The chief advantage of government regulation is that it includes more people in the process of making and enforcing the rules, thereby reducing the problem of conflicts of interest on the part of the profession itself. An important disadvantage is the uniformity and procedural complexity that normally characterize the legal process. These create difficulties in matching the rules to the variety of conflicts that may arise and could even decrease the probability that violations will be prevented or punished.

Whether the responsibility for dealing with conflicts of interest falls to individual physicians and researchers, the profession, or governments, **disclosure is the remedy most commonly prescribed.** A physician is required, for example, to tell patients about his or her financial interest in the laboratory to which they are being referred and to let them decide whether to go to a different laboratory. A scholar is expected to indicate the sources of financial support for the research. Disclosure may be more or less public; the information may be provided to colleagues, hospital or HMO administrators, professional boards, state boards, or the general public. An advantage of disclosure is that it gives those who would be affected, or who are otherwise in a good position to assess the risks, information they need to make their own decisions.

A **deficiency of disclosure** is that those who receive the information may not know how to interpret it and may not in any case have reasonable alternative courses of action in the circumstances[15,21]. Disclosure could even exacerbate some of the indirect consequences of conflicts, such as the effects on confidence in the profession or in the research enterprise. By itself, disclosure may merely increase levels of anxiety, causing patients and readers generally to suspect physicians and researchers but providing no constructive ways to restore trust. **Disclosing a conflict only reveals a problem, without providing any guidance for resolving it.**

Because of the limitations of disclosure, more stringent methods of enforcement deserve consideration, especially in cases of more severe kinds of conflict of interest. Other methods (roughly in order of increasing stringency) include mediation (devices such as blind trusts that insulate the physician from the secondary interest),[10,15] abstention (an analogue to judicial recusal that would have physicians or researchers withdraw from cases in which they have substantial secondary interests), divestiture (which would eliminate the secondary interest), and prohibition (which would have physicians or researchers withdraw permanently from fields in which they have substantial secondary interests)[15,22,23].

Conclusions

The problem of conflicts of interest in medicine is more complex than is often recognized. A more systematic framework is desirable for specifying and applying rules to regulate conflicts. A better understanding of the nature of conflicts of interest and a clearer formulation of standards could increase confidence in the medical profession. Physicians and scholars could then concentrate more fully on their main missions -- treating patients, teaching students, and conducting research.

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Reed Smith

MEMORANDUM

TO: HEALTH CARE CLIENTS

DATE: July 31, 2002

RE: Court Rules that Lithotripsy is Not Covered by Stark II Referral Ban

I. INTRODUCTION

On July 12, 2002, a federal court handed down a decision that exempted lithotripsy from the federal statute prohibiting physician self-referrals, commonly known as "Stark II" or the "Stark Law," 42 U.S.C. § 1395nn. The United States District Court for the District of Columbia (the "DC Court") held in American Lithotripsy Society et. al. v. Tommy G. Thompson, No. 01-01812 (D. DC, July 12, 2002), that when lithotripsy is furnished "under arrangements" with a hospital, it is not a "designated health service" ("DHS"), and, thus, referrals by physicians for lithotripsy are not subject to the Stark II prohibitions. This decision will affect both physicians who refer Medicare and Medicaid beneficiaries for lithotripsy, and the hospitals that provide such services. Moreover, the court's willingness to review and reverse the final regulations published by the Centers for Medicare and Medicaid Services ("CMS") interpreting Stark II, 66 Fed. Reg. 856 (Jan. 4, 2001) ("the Stark II/Phase I regulations"), could have significant ramifications for others in the health care industry. In addition, the standard for judicial review used by the district court may allow other challenges to Medicare regulations to proceed more readily. This decision is, of course, subject to appeal.

II. BACKGROUND

The lawsuit was brought by the American Lithotripsy Society and the Urology Society of America ("Plaintiffs") against CMS, contending that two regulatory provisions in the Stark II/Phase I regulations violated the Administrative Procedure Act, 5 U.S.C. § 706(2)(A)

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("APA"), and the Regulatory Flexibility Act, 5 U.S.C. § 601 (RFA). One provision related to the classification of lithotripsy as an inpatient or outpatient hospital service, which would make it subject to the Stark Law prohibitions as a DHS. The second provision concerned the methodology to be used for determining fair market value ("FMV") for lithotripsy services.

A. Lithotripsy

Lithotripsy is a medical procedure that removes kidney stones through the use of a machine called a lithotriptor, which uses shock waves to destroy the stones. These machines are very expensive, and many were purchased or leased by groups of urologists who own lithotripsy centers where they provide these services to patients. More than half of the lithotriptors in the country reportedly are owned by urologists.

CMS' current reimbursement methodology effectively forces lithotripsy services provided to Medicare beneficiaries to be furnished "under arrangements" with a hospital outpatient department. This methodology has developed because the established global rate for lithotripsy under Medicare's physician fee schedule does not currently incorporate a physician's overhead cost of the lithotripsy equipment. Therefore, the Medicare reimbursement system (as well as certain technological considerations) strongly discourages the provision of lithotripsy services in a physician office setting. In addition, although Congress and CMS designated lithotripsy as a procedure that could be performed in an ambulatory surgery center ("ASC"), CMS, after a decade of delay, still has not yet finalized the rate to be paid for lithotripsy in this setting. Therefore, ASCs currently cannot be paid for lithotripsy procedures performed in the ASCs. As a result, lithotripsy must be billed "under arrangements" with a hospital in order to obtain Medicare reimbursement for the "technical component." According to the DC Court, as a practical matter, this results in hospitals receiving up to 70 percent of the technical fees Medicare pays for the services provided, although the lithotripsy center typically furnishes all of the equipment and personnel, and the hospital does little more than bill Medicare.

B. The Stark Law and Regulations

The Stark Law prohibits physicians who have a financial relationship with an entity (or who have an immediate family member with a financial relationship) from making referrals for specified DHS to the entity unless the arrangements qualify for an exception. The original law, known as "Stark I," applied only to clinical laboratory services and sought to prevent the overutilization of laboratory services by physicians with a financial interest in ordering these services. Stark II extends the law to ten additional specified DHS, including inpatient and outpatient hospital services. The Stark II/Phase I regulations, which implement approximately

half of Stark II, generally became effective on January 4, 2002. The final regulations implementing the rest of Stark II are expected to be issued as part of "Phase II," possibly by the end of the year.

In the Stark II/Phase I regulations, CMS indicated that the provision of lithotripsy furnished "under arrangements" with a hospital would be considered to be an "inpatient or outpatient hospital service," and, therefore, a DHS. *See* 42 C.F.R. § 411.351; 66 Fed. Reg. at 940. Since urologists and other physicians who own lithotriptors or lithotripsy centers effectively were required by the Medicare reimbursement rules to provide lithotripsy services "under arrangements" with a hospital, these physicians essentially were required to have a financial arrangement with such hospitals.[1] As a result, since CMS was interpreting lithotripsy services to be a DHS, any referrals for lithotripsy by a physician (which were billed by the hospital providing the lithotripsy "under arrangements" with the physician or a physician-owned entity) would be subject to the complex requirements of the Stark law.

III. THE AMERICAN LITHOTRIPSY SOCIETY DECISION

In the lawsuit, Plaintiffs contended that CMS had impermissibly "bootstrapped" lithotripsy into the ambit of Stark II. The government took the position that lithotripsy was a DHS within the meaning of Stark II, as an inpatient or outpatient hospital service. In addition, the government claimed that the court could not hear the case until after it had gone through specified administrative review procedures (which would have delayed and possibly prevented the claims from ever being heard by a federal court).

A. Federal Question Jurisdiction

The DC Court held that federal question jurisdiction was proper in light of the standard set forth by the Supreme Court in Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1 (2000) ("Illinois Council").[2] The government had argued that the Illinois Council case required all claims "arising under" the Medicare statute to go through a designated administrative review process before the case could be brought before a court, citing

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1 The Stark II/Phase I regulations indicate that an "under arrangements" relationship would be considered to be a compensation arrangement. *See* 66 Fed. Reg. at 942.

2 For a more detailed discussion of this case, see our March 3, 2000 Client Memorandum entitled "U.S. Supreme Court Limits Federal Court Review of Medicare Challenges: *Shalala v. Illinois Counsel on Long Term Care, Inc.*"

42 U.S.C. § 405(h) ("Section 405(h)"). Under this interpretation, Plaintiffs would not have been able to obtain judicial review until after sanctions had been imposed by CMS.

The DC Court disagreed with the government, and found that the relevant question under Illinois Council was whether applying Section 405(h) in this context would have the practical effect of denying plaintiffs any form of judicial review. The DC Court held that requiring Plaintiffs to go through administrative channels as specified in Section 405(h) in this case would effectively eliminate judicial review for Plaintiffs' members due to: (i) the severity of penalties that might be incurred; and (ii) the limited access of Plaintiffs' member physicians to administrative review.

1. Draconian Penalties

The DC Court characterized the potential penalties at issue as "draconian" and "economic suicide," noting that violations of the Stark Law could result in monetary penalties of up to $15,000 per bill submitted to Medicare or Medicaid and disgorgement of payments previously received. The Court also noted Plaintiffs' assertion that they could be subject to potential criminal penalties and exclusion from participation in federal health care programs pursuant to 18 U.S.C. § 287 (false claims).

2. No Access to Judicial Review

According to the DC Court, Plaintiffs' members would have no standing to challenge the regulations at issue since they are not considered to be "providers" under the Medicare statute. The hospitals that provide the lithotripsy services "under arrangements" would have no incentive to contest the regulations since they benefit from them. Medicare beneficiaries also would have no interest in challenging these regulations because they will receive treatment from the physician regardless of how Medicare allocates reimbursement between the physician and the hospital. Finally, noting that the government had "not contested plaintiffs' allegations of potential financial ruin and lack of either direct access or an adequate proxy in the administrative process," the DC Court held that Section 405(h) did not preclude its jurisdiction in this case.

B. Ripeness

The government's claim that the case was not ripe for judicial review also was dismissed by the DC Court, citing cases which establish that the doctrine of "ripeness" does not prevent pre-enforcement review of regulations that are final and enforceable and which would cause substantial harm upon enforcement. The government also had contended that the case was not "ripe" for review because even if lithotripsy was held not to be a DHS, physicians who had

financial relationships with hospitals by providing them with lithotripsy services "under arrangements" still would be prohibited from referring patients for other inpatient and outpatient hospital services (which are DHS) to these hospitals, unless the arrangements satisfied a Stark II exception. Thus, even a decision favorable to the Plaintiffs would not fully remedy the alleged harm.

The DC Court rejected the government's ripeness argument and responded that it had to evaluate the challenged regulations with regard to lithotripsy. The court noted, among other things, that as a practical matter many physicians who owned lithotripsy centers did not make referrals for other types of inpatient or outpatient hospital services to the hospital. Thus, a ruling in this case could provide complete redress for these physicians.

C. The APA Challenge

In assessing whether CMS' regulatory interpretation of Stark II could survive an APA challenge, the DC Court employed the two-step analysis required under Chevron U.S.A. Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984). Under Chevron, the court first must determine whether Congress has spoken to the precise question at issue. If Congress' intent is clear, then the court must give effect to that intent. However, if congressional intent is ambiguous, the court must determine whether the regulation is based upon a permissible construction of the statute.

The DC Court found, contrary to the Stark II/Phase I regulations promulgated by CMS, that Congress clearly had intended that lithotripsy not be considered to be a DHS. The DC Court specifically held that:

> the lack of any mention of lithotripsy in the Stark II statute itself, the legislative history of the statute, and the statute's purpose demonstrate a clear intent on the part of Congress not to subject lithotripsy to the ban on self-referrals by including it in 'inpatient and outpatient hospital services.'

Further, the court stated that although lithotripsy had to be provided to Medicare beneficiaries through "under arrangements" contracts with a hospital, this requirement did not convert lithotripsy into a "hospital service" under Stark II. To find otherwise would be to (improperly) turn any health service with a remote connection to a hospital into an inpatient or outpatient hospital service subject to the Stark II prohibitions.

The court's holding also may have been influenced by what it perceived as several equitable factors, including that:

? The hospital's role in the lithotripsy situation generally is limited to serving as a "billing agent";

? The lithotripsy treatment often occurs without the patient setting foot in the hospital; and

? The primary reason that the service is provided "under arrangements" is because the government imposed this requirement, despite knowing it not to be medically necessary.

The DC Court similarly was unpersuaded that the text of the Stark Law itself mandated that lithotripsy be treated as an inpatient or outpatient hospital service since the procedure is not mentioned anywhere in the statute (which, in contrast, does mention other medical procedures, such as "magnetic resonance imaging," specifically by name). Moreover, the term "inpatient and outpatient hospital services" is not defined anywhere in Stark II or its predecessor Stark I. Finding that the Medicare statute also provides no greater clarity on this issue, the court turns to the legislative history and purpose of the statute. The DC Court cited the colloquy between Rep. Fortney "Pete" Stark and another member on the floor of the House of Representatives during the debate on the Stark Law in which Rep. Stark clearly stated that when physician-owned lithotripsy facilities furnished services under an arrangement with a hospital, those services were not to be considered DHS, and thus were not subject to the self-referral prohibitions as an inpatient or outpatient hospital service. *See* 139 Cong. Rec. H6238 (Aug. 5, 1993).

The court also examined the early legislative history of Stark I, which originally contained a blanket prohibition on all physician self-referrals but included a specific exception for lithotripsy. *See* H. Rep. No. 101-247 (1989). (The need for this exception later was obviated by Stark I's exclusive applicability to clinical laboratory services.) The DC Court further noted that Stark I was based on a Florida statute which similarly exempted lithotripsy because a study commissioned by the Florida Legislature had shown no risk of overutilization of lithotripsy associated with physician self-referrals. Finally, the DC Court dismissed the government's argument that Congress would have explicitly exempted lithotripsy from the list of DHS if that was what it intended, as "an attempt to turn the legislative history on its head."[3]

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3 The Court did not reach a determination on Plaintiff's challenge to another portion of the Stark II/Phase I regulations, and did not address the RFA issue since its analysis under the APA rendered those issues moot.

IV. DISCUSSION

Although the case likely will be appealed by the government, the DC Court's opinion may create some additional flexibility for providers seeking to interpret and comply with the Stark Law specifically, and Medicare regulations generally. The practical implications of the decision for lithotripsy providers are somewhat mixed. The DC Court clearly has held that referrals for lithotripsy will not implicate the Stark Law's prohibitions. However, physicians who own a lithotripsy center or other company that provides services to a hospital "under arrangements" apparently still have a financial relationship with the hospital under the Stark II/Phase I regulations. Thus a Stark exception still will have to apply if there are referrals to the hospital by these physicians for other DHS.

It is particularly important to note that the anti-kickback statute and other fraud and abuse laws still will be relevant in either case, *i.e.*, even when Stark II is not implicated by lithotripsy referrals. Thus, even if a physician refers only lithotripsy patients to the hospital that leases lithotripsy equipment from that physician or a related company, and the physician will not have to comply with a Stark exception, the arrangements still must be structured so as not to violate the anti-kickback statute. The physician therefore still should try to ensure that the lease arrangements comply with the equipment rental safe harbor to the anti-kickback statute. Nevertheless, unlike the "strict liability" Stark Law, the anti-kickback statute does not necessarily require compliance with all the criteria in a safe harbor if no purpose of the arrangement is to induce or reward referrals. Therefore, the American Lithotripsy Society case does provide some additional flexibility for the physicians who own lithotriptors/centers and the hospitals with which they contract. The situation could change even more dramatically if and when CMS revises its regulations to allow reimbursement for lithotripsy provided in physician offices/lithotripsy centers or ASCs. The DC Court's opinion may provide some additional incentive for CMS to implement such revisions. If this should happen, these physicians would potentially be able to eliminate their financial relationships with such hospitals, and thus business structures may become available under which neither the Stark Law nor the anti-kickback prohibitions would be implicated.

In addition, the American Lithotripsy Society decision raises the question of whether other services provided "under arrangements" with a hospital are not DHS, and therefore are not subject to the Stark Law's prohibitions. The DC Court's opinion seems to suggest such an argument might well be made, at least with regard to those services that are not otherwise designated as DHS.

The decision also is important because it signals the court's willingness to closely scrutinize the Stark II/Phase I regulations. The Stark Law and regulations are lengthy and extremely complex. There are few reported cases addressing the Stark Law, and few of them contain much analysis of the regulations. However, despite the detailed legal arguments presented by the government, the DC Court was willing to overturn CMS' interpretation of Stark II, relying heavily on the legislative history.[4] This is not the first instance where the Stark Law's legislative history conflicted with the agency's regulations. In fact, the Stark II/Phase I regulations reversed the position CMS had taken earlier in the proposed Stark II regulations, 63 Fed. Reg. 1659, prohibiting "per click" compensation, based on statements in the legislative history on this issue. Thus, providers may be well advised to review the legislative history when assessing their obligations under the Stark Law. This is particularly true in light of CMS' statement that it will accept "any reasonable interpretation" of the Stark Law's requirements during the period before the Stark II/Phase II regulations are issued.

Finally, the case indicates that providers may be able to obtain judicial review of these and various other issues that may arise under the Medicare statute where severe enforcement penalties are threatened, rather than having to first go through a time-consuming and expensive administrative review process, which often provides little, if any, relief.

* * * * *

Please do not hesitate to contact Linda Baumann (202/414-9488), Kevin Barry (202/414-9211), Karl Thallner (215/851-8171), Tim Ayers (215/851-8170), or any member of the Reed Smith health care group with whom you work if you would like additional information or if you have any questions.

The contents of this Memorandum are for informational purposes only, and do not constitute legal advice.

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4 It is important to note that the standard set by the American Lithotripsy Society decision is quite high. Before overturning a provision of the Stark II/Phase I regulations, the court found ambiguity in the statute as well as a substantial amount of clear legislative history with regard to lithotripsy, and Congress' intent to exempt it from the physician self-referral prohibitions. The DC Court also was likely influenced by the equities which seemed to weigh heavily in favor of the physician-owners due to the low risk of overutilization of lithotripsy services, and because these physicians only provide lithotripsy "under arrangements" with hospitals because of Medicare's reimbursement requirements (which are not based on medical necessity), and CMS' delay in implementing other appropriate reimbursement methodologies for this procedure.

Office of Inspector General News

Office of Inspector General
Department of Health and Human Services
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For Immediate Release
July 8, 2010
Phone Number: 202/619-1343

OIG Enters Into $7.3 Million Civil Monetary Penalty Settlement With Physician-Owned Enterprise

Washington, DC – The Office of Inspector General (OIG) for the Department of Health and Human Services today entered into a Civil Monetary Penalty (CMP) settlement agreement with United Shockwave Services, United Prostate Centers, and United Urology Centers (collectively, United), all based in the Chicago, Illinois area. The agreement settles charges that, by soliciting and receiving payments from hospitals in exchange for patient referrals, United violated Federal anti-kickback laws.

Specifically, OIG alleged that United, and certain of its physician-owners, leveraged patient referrals to obtain contract business from hospitals in Illinois, Indiana, and Iowa. OIG also alleged that United caused certain hospitals to submit claims for designated health services that resulted from prohibited referrals in violation of the Physician Self-Referral Law (Stark law).

United provides hospitals with lithotripsy and laser services and equipment. Lithotripsy uses high-energy shockwave therapy to crush kidney stones, and the high-powered laser services are used to treat men with enlarged prostates.

"This settlement sends a strong message that companies, including those with physician-owners, cannot use Federal health care beneficiary referrals to line their pockets by securing business from hospitals or other providers," said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. "We continue to have serious kickback concerns when companies link investment opportunities to the ability to generate business and offer returns on investment that are disproportionate to business risk."

United entered into a 5-year Corporate Integrity Agreement (CIA) in conjunction with the $7.3 million settlement. Under the CIA, United is required to hire an Independent Review Organization. The independent reviewer will monitor lithotripsy and laser arrangements between United and any hospital in Illinois, Iowa, and Indiana that receives referrals from United or its physician investors. United is also required to create a comprehensive training program to educate its employees and corporate members on Stark law and kickback issues.

In resolving this matter through a settlement agreement, United has denied any liability.

This settlement resulted from an investigation conducted by OIG attorneys Brian Bewley, Kevin Barry, Tamara Forys, and OIG Special Agent Raul Sese.

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[NOTE TO EDITORS/REPORTERS: You may request a copy of the settlement agreement through the OIG Freedom of Information Act Office at:
http://www.oig.hhs.gov/foia/submit.asp]

To see the Corporate Integrity Agreement:
http://oig.hhs.gov/fraud/cia/agreements/united_shockwave_07082010.pdf

11-CV-10090

HON VICTORIA ROBERTS

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COUNCIL FOR UROLOGICAL INTERESTS **Plaintiff,** **v.** **KATHLEEN SEBELIUS, in her official capacity as Secretary of the Department of Health and Human Services** **and** **United States of America,** **Defendants.**	**Civ. No. 1:09-cv-00546-BJR**

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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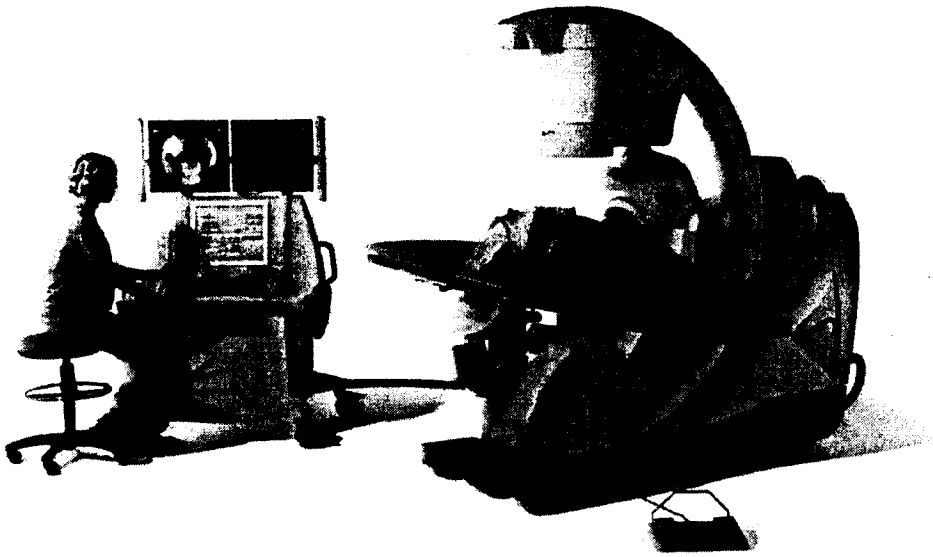
PATIENT INFORMATION GUIDE
Lithotripsy Treatment

What are Kidney Stones?
Kidney Stones are crystal-like masses of salts and minerals, such as calcium in combination with either oxalate or phosphate, such as calcium oxalate, that form when the crystals precipitate in the urine inside the kidney. Stones can vary in size from a grain of sand to more than an inch in diameter. They build up gradually, and can stay in your kidneys or can be found anywhere in the urinary tract. A number of factors are thought to influence the development of kidney stones. Doctors do not always know what causes a stone to form. Some suggested causes are diet, climate, infection and metabolic disorders.

When stones grow too large to pass out of the body naturally, they can obstruct normal urine flow and may cause sudden and severe pain. Other symptoms may include bloody urine, burning during urination, infection, nausea and vomiting. Permanent relief can only be gained by removal of the stones.

What is Extracorporeal Shockwave Lithotripsy?
"Lithotripsy," from the Greek meaning "stone crushing," is a application of technology for treating stones in the kidneys, ureters and bladder. The term "extracorporeal" refers to the fact that the treatment is non-invasive, using shockwaves directed from outside the body. The stone to be treated is targeted with the use of x-ray or ultrasound. Multiple high-energy pressure waves are then focused on the stone until it breaks into tiny particles, which can be passed naturally from the urinary system.



What are the Benefits of Extracorporeal Shockwave Lithotripsy?
A major benefit of extracorporeal shockwave lithotripsy is that it is a non-invasive procedure. Lithotripsy is usually performed on an outpatient basis with reduced treatment and recovery times.

What are the Risks Associated with Extracorporeal Shockwave Lithotripsy?
Lithotripsy is usually safe. Historically, occurrence of complications is low. Possible complications can include bleeding around your kidney, kidney infection or pieces of stone left behind.

PATIENT INFORMATION GUIDE
Lithotripsy Treatment

What Happens Before the Lithotripsy Procedure?

Some laboratory tests are required prior to your procedure. The tests will vary; however, depending upon the type of anesthesia, if any, you will receive during treatment, your age, any medical conditions you may have or any medications you take. Some medications must be discontinued prior to treatment.

Follow your physician's specific instructions regarding eating or drinking prior to your treatment. You will be informed by your physician about the procedure to be performed and you will be asked to sign an informed consent for this procedure.

What Happens During the Procedure?

Your treatment will typically proceed in the following manner:

- You will be comfortably positioned on the patient treatment table.
- An x-ray will be taken to determine the precise location of the stone(s).
- The shockwave applicator will be placed against the side of your body. The applicator will direct a series of wave impulses through your body, fragmenting the stones, until they are pulverized.
- While being treated with lithotripsy, your anesthesiologist or nurse will care for you to make sure that you are comfortable and safe during the treatment. The treatment will last 30 - 45 minutes.
- Your physician will follow the fragmentation process via video x-ray equipment and carefully monitor the entire procedure.
- Mild soreness may occur at the treatment site after lithotripsy. In some instances, you may never know that you had lithotripsy.

What Happens After the Procedure?

- After the procedure, you will remain in the recovery area until the medication given during treatment wears off.
- You may have soreness in the back or flank area. This usually disappears after several days. The treatment can cause blotches or bruises on the back where the pressure wave enters the skin. These marks usually cause only minimal discomfort and should disappear in a short time.
- You will most likely have some pain after treatment, as the pulverized fragments of stone are passed down the tube from the kidney to the urinary bladder. Pain medication prescribed by your doctor should help with this discomfort.
- A small percentage of patients may have severe pain and/or obstruction from the failure of the stone fragments to pass.
- Your urine may have a red tinge for several days after treatment, but blood loss is usually minimal.
- Stone fragments should begin to pass within 24 hours of treatment, although a delayed passage is not unusual.
- If your stone is greater than one inch in diameter or if you have multiple stones that have an aggregate diameter greater than one inch, you may require more than one treatment.
- You will receive specific written aftercare instructions when you are ready to go home.
- Because you have received medications during your treatment, you must have someone drive you home.

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11-CV-10090

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HealthTronics

9825 Spectrum Drive, Building 3
Austin, TX 78717
(888) 252-6575
www.HealthTronics.com

KIDNEY STONE CENTER
Health ONE
1721 East 19th Ave. #172
Denver, CO 80218

PATIENT INFORMED CONSENT

Extracorporeal Shock Wave Lithotripsy (ESWL) is a technique to treat urinary stone. The goal of this treatment is to pulverize urinary stones into sand-sized particles small enough to be passed out through the urinary tract. I understand that there are alternative methods to treat urinary stones, which include:

A. No treatment of the urinary stone(s).
B. Manipulation of a stone in the ureter back into the kidney with placement of a tube for urinary drainage.
C. Internal (scope) examination of the urinary bladder and/or ureter with possible retrieval of stones in the ureter including possible laser fragmentation.
D. Percutaneous Lithotripsy (PNL), a puncture/scope technique through the side directly into the kidney.
E. Surgical removal of stone(s) through an incision.

I realize that ESWL **MAY or MAY NOT** successfully fragment my stones. I further realize that successful ESWL treatment may result in stone fragments of varying size and that some fragments may be too large to pass easily or at all. I recognize that some stones will require the placement of a tube into my kidney, either through the bladder or through my side to facilitate passage of fragments before ESWL is done. I further recognize that some fragments may require any or all of the above alternative treatments to be used following ESWL including possible repeat ESWL. I understand that radiographs (x-rays) and other diagnostic studies are necessary following ESWL to assess the success of treatment and to diagnose urinary drainage problems, which might result from ESWL. I understand that any tubes placed in my urinary tract before, during and after ESWL treatment will need to be removed in a timely fashion.

RISKS OF ESWL

A. The stone may be incompletely fragmented and require alternative treatment.
B. There may be bruising of tissue along the path of the shock wave.
C. There may be bleeding from ESWL sufficient enough to require transfusion.
D. Damage to kidney has occurred and may require the removal of the kidney.
E. Urinary infection associated with stones may become aggravated and become life threatening.
F. Death is a rare possibility.
G. Machine malfunction may occur necessitating removal from the lithotripter, rescheduling of your treatment and anesthetic.

THESE ARE NOT PROBABLE RESULTS, BUT THEY ARE STATISTICAL POSSIBLITIES.

PREGNANCY

I understand that ESWL should not be performed if I am pregnant. A pregnancy test is required on **ALL** women where pregnancy is a possibility.

PATIENT ACKNOWLEDGEMENT

I understand that my medical care will be provided by a team of physicians consisting of my personal physician, (urologist), or urologists working under the auspices of the Kidney Stone Center.

I have been given an opinion as to the appropriateness of ESWL for my condition by my personal physician and a second opinion by the Kidney Stone Center physician(s). I have been given the right to a third opinion if I so desire.

If my personal urologist is a participating member of the Kidney Stone Center, they and the urologists at the center have agreed to share my care and the professional fees paid by me or my insurance carrier for such care. I understand that it is my responsibility to seek follow-up care from my personal physician after ESWL treatment. I will be given instructions on necessary post-treatment care.

I have been allowed to ask questions about the treatment. I have read this form and/or it has been explained to me. I understand that be signing this form, I am consenting to the performance of ESWL upon my urinary stones and any of the above-mentioned alternative procedures necessary for my best health. I further acknowledge that the medical information I have provided the Kidney Stone Center is accurate and that I have disclosed any uncertainty concerning its accuracy and have been informed of the importance of providing complete and accurate information. As to any incomplete or possibly inaccurate information, I have been given both the means and the opportunity to check the information, which I believe, may be inaccurate. By signing this document, I agree that any problems, risks, or complications, which may arise either in whole or in part as a result of inaccurate or incomplete information shall be my responsibility.

"I hereby acknowledge specifically that I have been provided no guarantees, promises, or warranties of any kind in regard to ESWL."

_____
Anatomic Location of Kidney Stone (physician to complete)

I have read this authorization: _____
PT. Initials

I understand this authorization: _____
PT. Initials

My questions about my procedure have been answered: _____
PT. Initials

Patient Signature	Physician Signature	Date
_____	_____	_____

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10A NCAC 14C .3205 STAFFING AND STAFF TRAINING

(a) The applicant shall demonstrate that the following staff shall be available at each location at which the lithotriptor will be operated:

(1) one certified general surgeon;

(2) one certified urologist skilled and experienced in complicated stone disease treatment capability; and

(3) one certified radiologist with experience in X-ray, CT and Ultrasound Imaging.

(b) All individuals using the lithotriptor equipment shall obtain Quality Assurance and Training Certification from the American Lithotripsy Society or shall meet the training and proficiency guidelines and standards in the American Urological Association Guidelines and Standards, which are hereby incorporated by reference, including all subsequent amendments and editions of the referenced materials. A list of the American Urological Association's approved training sites may be obtained free of charge from American Urological Association, 1120 North Charles Street, Baltimore, Maryland, 21201. The schedule for offering Quality Assurance and Training Certification by the American Lithotripsy Society may be obtained free of charge from the American Lithotripsy Society, Thirteen Elm Street, Manchester, MA 01944.

(c) The applicant shall demonstrate that the following staff training shall be provided at each location where the lithotriptor will be operated:

(1) certification in cardiopulmonary resuscitation and basic cardiac life support; and

(2) an organized program of staff education and training specific to lithotriptor services that ensures improvements in technique and the proper training of new personnel.

History Note: *Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*
Statutory Authority G.S. 131E-177(1); 131E-183(b);
Eff. January 4, 1994.

Form **990**

Department of the Treasury
Internal Revenue Service

Return of Organization Exempt From Income Tax

Under section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code (except black lung benefit trust or private foundation)

▶ The organization may have to use a copy of this return to satisfy state reporting requirements.

OMB No. 1545-0047

2004

Open to Public Inspection

A For the 2004 calendar year, or tax year beginning and ending

B Check if applicable:
- ☐ Address change
- ☐ Name change
- ☐ Initial return
- ☐ Final return
- ☐ Amended return
- ☐ Application pending

Please use IRS label or print or type. See Specific Instructions.

C Name of organization: AMERICAN LITHOTRIPSY SOCIETY

Number and street (or P.O. box if mail is not delivered to street address): 305 SECOND AVENUE — Room/suite: 200

City or town, state or country, and ZIP + 4: WALTHAM, MA 02451

D Employer identification number: 56-1558234

E Telephone number: 781-895-9098

F Accounting method: ☒ Cash ☐ Accrual ☐ Other (specify) ▶

● Section 501(c)(3) organizations and 4947(a)(1) nonexempt charitable trusts must attach a completed Schedule A (Form 990 or 990-EZ).

H and I are not applicable to section 527 organizations.

H(a) Is this a group return for affiliates? ☐ Yes ☒ No

H(b) If "Yes," enter number of affiliates ▶

H(c) Are all affiliates included? N/A ☐ Yes ☐ No (If "No," attach a list.)

H(d) Is this a separate return filed by an organization covered by a group ruling? ☐ Yes ☒ No

G Website: ▶WWW.LITHOTRIPSY.ORG

J Organization type (check only one) ▶ ☒ 501(c) (6) ◀ (insert no.) ☐ 4947(a)(1) or ☐ 527

K Check here ▶ ☐ if the organization's gross receipts are normally not more than $25,000. The organization need not file a return with the IRS; but if the organization received a Form 990 Package in the mail, it should file a return without financial data. Some states require a complete return.

I Group Exemption Number ▶

L Gross receipts: Add lines 6b, 8b, 9b, and 10b to line 12 ▶ 322,562.

M Check ▶ ☐ if the organization is not required to attach Sch. B (Form 990, 990-EZ, or 990-PF).

Part I Revenue, Expenses, and Changes in Net Assets or Fund Balances

1	Contributions, gifts, grants, and similar amounts received:			
a	Direct public support	1a	30,555.	
b	Indirect public support	1b		
c	Government contributions (grants)	1c		
d	Total (add lines 1a through 1c) (cash $ 30,555. noncash $)			1d 30,555.
2	Program service revenue including government fees and contracts (from Part VII, line 93)			2 70,715.
3	Membership dues and assessments			3 221,270.
4	Interest on savings and temporary cash investments			4 22.
5	Dividends and interest from securities			5
6 a	Gross rents	6a		
b	Less: rental expenses	6b		
c	Net rental income or (loss) (subtract line 6b from line 6a)			6c
7	Other investment income (describe ▶)			7
8 a	Gross amount from sales of assets other than inventory — (A) Securities	8a	(B) Other	
b	Less: cost or other basis and sales expenses	8b		
c	Gain or (loss) (attach schedule)	8c		
d	Net gain or (loss) (combine line 8c, columns (A) and (B))			8d
9	Special events and activities (attach schedule). If any amount is from gaming, check here ▶ ☐			
a	Gross revenue (not including $ of contributions reported on line 1a)	9a		
b	Less: direct expenses other than fundraising expenses	9b		
c	Net income or (loss) from special events (subtract line 9b from line 9a)			9c
10 a	Gross sales of inventory, less returns and allowances	10a		
b	Less: cost of goods sold	10b		
c	Gross profit or (loss) from sales of inventory (attach schedule) (subtract line 10b from line 10a)			10c
11	Other revenue (from Part VII, line 103)			11
12	Total revenue (add lines 1d, 2, 3, 4, 5, 6c, 7, 8d, 9c, 10c, and 11)			12 322,562.
13	Program services (from line 44, column (B))			13 218,985.
14	Management and general (from line 44, column (C))			14 123,396.
15	Fundraising (from line 44, column (D))			15
16	Payments to affiliates (attach schedule)			16
17	Total expenses (add lines 16 and 44, column (A))			17 342,381.
18	Excess or (deficit) for the year (subtract line 17 from line 12)			18 -19,819.
19	Net assets or fund balances at beginning of year (from line 73, column (A))			19 15,490.
20	Other changes in net assets or fund balances (attach explanation)			20 0.
21	Net assets or fund balances at end of year (combine lines 18, 19, and 20)			21 -4,329.

Expenses

Net Assets

SCANNED OCT 03 2005

RECEIVED SEP 19 2005 IRS OGDEN, UT

423001 01-13-05 LHA For Privacy Act and Paperwork Reduction Act Notice, see the separate instructions. Form 990 (2004)

1

14440906 757939 300024 11:CV-10090 2004.05080 AMERICAN LITHOTRIPSY SOCIET 300024_1

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AMERICAN LITHOTRIPSY SOCIETY 56-1558234

Part II Statement of Functional Expenses All organizations must complete column (A). Columns (B), (C), and (D) are required for section 501(c)(3) and (4) organizations and section 4947(a)(1) nonexempt charitable trusts but optional for others. Page 2

Do not include amounts reported on line 6b, 8b, 9b, 10b, or 16 of Part I.		(A) Total	(B) Program services	(C) Management and general	(D) Fundraising
22 Grants and allocations (attach schedule) (cash $ _____ noncash $ _____)	22				
23 Specific assistance to individuals (attach schedule)	23				
24 Benefits paid to or for members (attach schedule)	24				
25 Compensation of officers, directors, etc.	25	0.	0.	0.	0.
26 Other salaries and wages	26				
27 Pension plan contributions	27				
28 Other employee benefits	28				
29 Payroll taxes	29				
30 Professional fundraising fees	30				
31 Accounting fees	31				
32 Legal fees	32				
33 Supplies	33	176.		176.	
34 Telephone	34	6,319.		6,319.	
35 Postage and shipping	35	5,547.		5,547.	
36 Occupancy	36				
37 Equipment rental and maintenance	37				
38 Printing and publications	38	2,546.		2,546.	
39 Travel	39				
40 Conferences, conventions, and meetings	40	190,882.	190,882.		
41 Interest	41	48.		48.	
42 Depreciation, depletion, etc. (attach schedule)	42				
43 Other expenses not covered above (itemize):					
a _____	43a				
b _____	43b				
c _____	43c				
d _____	43d				
e SEE STATEMENT 1	43e	136,863.	28,103.	108,760.	
44 Total functional expenses (add lines 22 through 43). Organizations completing columns (B)-(D), carry these totals to lines 13-15.	44	342,381.	218,985.	123,396.	0.

Joint Costs. Check ▶ ☐ if you are following SOP 98-2.

Are any joint costs from a combined educational campaign and fundraising solicitation reported in (B) Program services? ▶ ☐ Yes ☒ No

If "Yes," enter (i) the aggregate amount of these joint costs $ _____ ; (ii) the amount allocated to Program services $ _____ ;

(iii) the amount allocated to Management and general $ _____ ; and (iv) the amount allocated to Fundraising $ _____

Part III Statement of Program Service Accomplishments

What is the organization's primary exempt purpose? ▶ SEE STATEMENT 2

All organizations must describe their exempt purpose achievements in a clear and concise manner. State the number of clients served, publications issued, etc. Discuss achievements that are not measurable. (Section 501(c)(3) and (4) organizations and 4947(a)(1) nonexempt charitable trusts must also enter the amount of grants and allocations to others.)

Program Service Expenses (Required for 501(c)(3) and (4) orgs., and 4947(a)(1) trusts; but optional for others.)

a ANNUAL MEETING - PROVIDE MEMBERS WITH CLINICAL PRESENTATIONS AND FORUMS FEATURING DISCUSSIONS PERTAINING TO URINARY AND BILIARY LITHOTRIPSY, LONG TERM RESULTS, AND EFFICACY OF CURRENT TECHNOLOGY. (Grants and allocations $) 190,882.

b LEGAL & PROFESSIONAL FEES - FOR COSTS ASSOCIATED WITH GOVERNMENTAL AFFAIRS MONITORING ACTIVITY AND STATISTICAL RESEARCH (Grants and allocations $) 14,327.

c OFFICERS AND COMMITTEES - PERIODIC MEETING TO UPDATE THE SOCIETY WITH THE LATEST MEDICAL TECHNOLOGIES. (Grants and allocations $) 10,653.

d OTHER PROGRAM SERVICES RELATED TO QUALITY AND CERTIFICATION PROGRAMS OF THE SOCIETY. (Grants and allocations $) 3,123.

e Other program services (attach schedule) (Grants and allocations $)

f Total of Program Service Expenses (should equal line 44, column (B), Program services) ▶ 218,985.

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Part IV Balance Sheets

Note: Where required, attached schedules and amounts within the description column should be for end-of-year amounts only.			(A) Beginning of year		(B) End of year
Assets	45 Cash - non-interest-bearing		5,814.	45	123.
	46 Savings and temporary cash investments		9,676.	46	548.
	47 a Accounts receivable	47a			
	b Less: allowance for doubtful accounts	47b		47c	
	48 a Pledges receivable	48a			
	b Less: allowance for doubtful accounts	48b		48c	
	49 Grants receivable			49	
	50 Receivables from officers, directors, trustees, and key employees			50	
	51 a Other notes and loans receivable	51a			
	b Less: allowance for doubtful accounts	51b		51c	
	52 Inventories for sale or use			52	
	53 Prepaid expenses and deferred charges			53	
	54 Investments - securities ▶ ☐ Cost ☐ FMV			54	
	55 a Investments - land, buildings, and equipment: basis	55a			
	b Less: accumulated depreciation	55b		55c	
	56 Investments - other			56	
	57 a Land, buildings, and equipment: basis	57a			
	b Less: accumulated depreciation	57b		57c	
	58 Other assets (describe ▶)			58	
	59 Total assets (add lines 45 through 58) (must equal line 74)		15,490.	59	671.
Liabilities	60 Accounts payable and accrued expenses			60	
	61 Grants payable			61	
	62 Deferred revenue			62	
	63 Loans from officers, directors, trustees, and key employees STMT 3			63	5,000.
	64 a Tax-exempt bond liabilities			64a	
	b Mortgages and other notes payable			64b	
	65 Other liabilities (describe ▶)			65	
	66 Total liabilities (add lines 60 through 65)		0.	66	5,000.
Net Assets or Fund Balances	Organizations that follow SFAS 117, check here ▶ ☒ and complete lines 67 through 69 and lines 73 and 74.				
	67 Unrestricted		4,464.	67	-21,583.
	68 Temporarily restricted		11,026.	68	17,254.
	69 Permanently restricted			69	
	Organizations that do not follow SFAS 117, check here ▶ ☐ and complete lines 70 through 74.				
	70 Capital stock, trust principal, or current funds			70	
	71 Paid-in or capital surplus, or land, building, and equipment fund			71	
	72 Retained earnings, endowment, accumulated income, or other funds			72	
	73 Total net assets or fund balances (add lines 67 through 69 or lines 70 through 72; column (A) must equal line 19; column (B) must equal line 21)		15,490.	73	-4,329.
	74 Total liabilities and net assets / fund balances (add lines 66 and 73)		15,490.	74	671.

Form 990 is available for public inspection and, for some people, serves as the primary or sole source of information about a particular organization. How the public perceives an organization in such cases may be determined by the information presented on its return. Therefore, please make sure the return is complete and accurate and fully describes, in Part III, the organization's programs and accomplishments.

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Part IV-A Reconciliation of Revenue per Audited Financial Statements with Revenue per Return

a Total revenue, gains, and other support per audited financial statements	a	N/A
b Amounts included on line a but not on line 12, Form 990:		
(1) Net unrealized gains on investments $		
(2) Donated services and use of facilities $		
(3) Recoveries of prior year grants $		
(4) Other (specify): $		
Add amounts on lines (1) through (4)	b	
c Line a minus line b	c	
d Amounts included on line 12, Form 990 but not on line a:		
(1) Investment expenses not included on line 6b, Form 990 $		
(2) Other (specify): $		
Add amounts on lines (1) and (2)	d	
e Total revenue per line 12, Form 990 (line c plus line d)	e	

Part IV-B Reconciliation of Expenses per Audited Financial Statements with Expenses per Return

a Total expenses and losses per audited financial statements	a	N/A
b Amounts included on line a but not on line 17, Form 990:		
(1) Donated services and use of facilities $		
(2) Prior year adjustments reported on line 20, Form 990 $		
(3) Losses reported on line 20, Form 990 $		
(4) Other (specify): $		
Add amounts on lines (1) through (4)	b	
c Line a minus line b	c	
d Amounts included on line 17, Form 990 but not on line a:		
(1) Investment expenses not included on line 6b, Form 990 $		
(2) Other (specify): $		
Add amounts on lines (1) and (2)	d	
e Total expenses per line 17, Form 990 (line c plus line d)	e	

Part V List of Officers, Directors, Trustees, and Key Employees (List each one even if not compensated.)

(A) Name and address	(B) Title and average hours per week devoted to position	(C) Compensation (If not paid, enter -0-.)	(D) Contributions to employee benefit plans & deferred compensation	(E) Expense account and other allowances
G. KENNETH SCHOLL JR., M.D. 305 SECOND AVENUE WALTHAM, MA 02451	PAST PRESIDENT 2	0.	0.	0.
ROBERT I. BARSKY, DO,FACS 305 SECOND AVENUE WALTHAM, MA 02451	PRESIDENT-ELECT 2	0.	0.	0.
BARRY ROSSMAN, M.D. 305 SECOND AVENUE WALTHAM, MA 02451	SECRETARY 2	0.	0.	0.
DAVID ALLEN, M.D. 305 SECOND AVENUE WALTHAM, MA 02451	PRESIDENT 2	0.	0.	0.
PHILIP MOSCA, PH.D.,M.D. 305 SECOND AVENUE WALTHAM, MA 02451	TREASURER 2	0.	0.	0.
THERESA PERRY, R.N., CRLS 305 SECOND AVENUE WALTHAM, MA 02451	PRESIDENT-ALLIED SECTION 2	0.	0.	0.
WESLEY HARRINGTON, CAE 305 SECOND AVENUE WALTHAM, MA 02451	EXECUTIVE DIRECTOR 2	0.	0.	0.
EUGENE GENTILE, R.T., CRLS 305 SECOND AVENUE WALTHAM, MA 02451	PRESIDENT-ELECT ALLIED SEC 2	0.	0.	0.
PAUL W.F. COUGHLIN, MD 305 SECOND AVENUE WALTHAM, MA 02451	USA REPRESENTATIVE 2	0.	0.	0.

75 Did any officer, director, trustee, or key employee receive aggregate compensation of more than $100,000 from your organization and all related organizations, of which more than $10,000 was provided by the related organizations? If "Yes," attach schedule. ▶ ☐ Yes ☒ No

Part VI Other Information

			Yes	No
76	Did the organization engage in any activity not previously reported to the IRS? If "Yes," attach a detailed description of each activity	76		X
77	Were any changes made in the organizing or governing documents but not reported to the IRS? If "Yes," attach a conformed copy of the changes.	77		X
78 a	Did the organization have unrelated business gross income of $1,000 or more during the year covered by this return?	78a		X
b	If "Yes," has it filed a tax return on Form 990-T for this year? N/A	78b		
79	Was there a liquidation, dissolution, termination, or substantial contraction during the year? If "Yes," attach a statement	79		X
80 a	Is the organization related (other than by association with a statewide or nationwide organization) through common membership, governing bodies, trustees, officers, etc., to any other exempt or nonexempt organization?	80a	X	
b	If "Yes," enter the name of the organization ▶ UROLOGY SOCIETY OF AMERICA and check whether it is [X] exempt or [ ] nonexempt.			
81 a	Enter direct or indirect political expenditures. See line 81 instructions 81a 0.			
b	Did the organization file Form 1120-POL for this year?	81b		X
82 a	Did the organization receive donated services or the use of materials, equipment, or facilities at no charge or at substantially less than fair rental value?	82a	X	
b	If "Yes," you may indicate the value of these items here. Do not include this amount as revenue in Part I or as an expense in Part II. (See instructions in Part III.) 82b			
83 a	Did the organization comply with the public inspection requirements for returns and exemption applications?	83a	X	
b	Did the organization comply with the disclosure requirements relating to quid pro quo contributions?	83b	X	
84 a	Did the organization solicit any contributions or gifts that were not tax deductible?	84a		X
b	If "Yes," did the organization include with every solicitation an express statement that such contributions or gifts were not tax deductible? N/A	84b		
85	*501(c)(4), (5), or (6) organizations.* a Were substantially all dues nondeductible by members?	85a		X
b	Did the organization make only in-house lobbying expenditures of $2,000 or less?	85b	X	
	If "Yes" was answered to either 85a or 85b, do not complete 85c through 85h below unless the organization received a waiver for proxy tax owed for the prior year.			
c	Dues, assessments, and similar amounts from members 85c N/A			
d	Section 162(e) lobbying and political expenditures 85d N/A			
e	Aggregate nondeductible amount of section 6033(e)(1)(A) dues notices 85e N/A			
f	Taxable amount of lobbying and political expenditures (line 85d less 85e) 85f N/A			
g	Does the organization elect to pay the section 6033(e) tax on the amount on line 85f? N/A	85g		
h	If section 6033(e)(1)(A) dues notices were sent, does the organization agree to add the amount on line 85f to its reasonable estimate of dues allocable to nondeductible lobbying and political expenditures for the following tax year? N/A	85h		
86	*501(c)(7) organizations.* Enter: a Initiation fees and capital contributions included on line 12 86a N/A			
b	Gross receipts, included on line 12, for public use of club facilities 86b N/A			
87	*501(c)(12) organizations.* Enter: a Gross income from members or shareholders 87a N/A			
b	Gross income from other sources. (Do not net amounts due or paid to other sources against amounts due or received from them.) 87b N/A			
88	At any time during the year, did the organization own a 50% or greater interest in a taxable corporation or partnership, or an entity disregarded as separate from the organization under Regulations sections 301.7701-2 and 301.7701-3? If "Yes," complete Part IX	88		X
89 a	*501(c)(3) organizations.* Enter: Amount of tax imposed on the organization during the year under: section 4911 ▶ N/A ; section 4912 ▶ N/A ; section 4955 ▶ N/A			
b	*501(c)(3) and 501(c)(4) organizations.* Did the organization engage in any section 4958 excess benefit transaction during the year or did it become aware of an excess benefit transaction from a prior year? If "Yes," attach a statement explaining each transaction N/A	89b		
c	Enter: Amount of tax imposed on the organization managers or disqualified persons during the year under sections 4912, 4955, and 4958 ▶ N/A			
d	Enter: Amount of tax on line 89c, above, reimbursed by the organization ▶ N/A			
90 a	List the states with which a copy of this return is filed ▶ NORTH CAROLINA			
b	Number of employees employed in the pay period that includes March 12, 2004 90b 0			
91	The books are in care of ▶ WESLEY E. HARRINGTON Telephone no. ▶ 781-895-9098			
	Located at ▶ 305 SECOND AVE, SUITE 200 , WALTHAM, MA ZIP + 4 ▶ 02451			
92	*Section 4947(a)(1) nonexempt charitable trusts filing Form 990 in lieu of* Form 1041 - Check here ▶ [ ] and enter the amount of tax-exempt interest received or accrued during the tax year ▶ 92 0.			

Part VII Analysis of Income-Producing Activities (See page 33 of the instructions.)

Note: Enter gross amounts unless otherwise indicated.	Unrelated business income (A) Business code	Unrelated business income (B) Amount	Excluded by section 512, 513, or 514 (C) Exclusion code	Excluded by section 512, 513, or 514 (D) Amount	(E) Related or exempt function income
93 Program service revenue:					
a ANNUAL MEETINGS			07	55,700.	
b TRAINING MANUAL					920.
c RENAL CERTIFICATION					9,095.
d QUALITY IMPROVEMENT					
e CERTIFICATION					5,000.
f Medicare/Medicaid payments					
g Fees and contracts from government agencies					
94 Membership dues and assessments					221,270.
95 Interest on savings and temporary cash investments			14	22.	
96 Dividends and interest from securities					
97 Net rental income or (loss) from real estate:					
a debt-financed property					
b not debt-financed property					
98 Net rental income or (loss) from personal property					
99 Other investment income					
100 Gain or (loss) from sales of assets other than inventory					
101 Net income or (loss) from special events					
102 Gross profit or (loss) from sales of inventory					
103 Other revenue:					
a					
b					
c					
d					
e					
104 Subtotal (add columns (B), (D), and (E))		0.		55,722.	236,285.
105 Total (add line 104, columns (B), (D), and (E)) ▶					292,007.

Note: *Line 105 plus line 1d, Part I, should equal the amount on line 12, Part I.*

Part VIII Relationship of Activities to the Accomplishment of Exempt Purposes (See page 34 of the instructions.)

Line No. ▼	Explain how each activity for which income is reported in column (E) of Part VII contributed importantly to the accomplishment of the organization's exempt purposes (other than by providing funds for such purposes).
93B C&D	TO REVIEW PROCEDURES AND EQUIPMENT AT SITE LOCATIONS AND TO CERTIFY PERSONNEL AND MEMBERS.
94	DUES AND ASSESSMENTS ARE USED TO SUPPLEMENT THE ANNUAL MEETING AND SERVICE EXPENSES.

Part IX Information Regarding Taxable Subsidiaries and Disregarded Entities (See page 34 of the instructions.)

(A) Name, address, and EIN of corporation, partnership, or disregarded entity	(B) Percentage of ownership interest	(C) Nature of activities	(D) Total income	(E) End-of-year assets
	%			
N/A	%			
	%			
	%			

Part X Information Regarding Transfers Associated with Personal Benefit Contracts (See page 34 of the instructions.)

(a) Did the organization, during the year, receive any funds, directly or indirectly, to pay premiums on a personal benefit contract? ☐ Yes ☒ No

(b) Did the organization, during the year, pay premiums, directly or indirectly, on a personal benefit contract? ☐ Yes ☒ No

Note: *If "Yes" to (b), file Form 8870 and Form 4720 (see instructions).*

Please Sign Here — Under penalties of perjury, I declare that I have examined this return, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, [redacted] information of which preparer has any knowledge.

9/13/05 Date ▶ Philip Mosca MD - Treasurer Type or print name and title.

[redacted] CPA Date 9/6/05 Check if self-employed ▶ ☐ Preparer's SSN or PTIN P00068702

[redacted]

HON VICTORIA ROBERTS 11-CV-10090

800153

AMERICAN LITHOTRIPSY SOCIETY 56-1558234

FORM 990 OTHER EXPENSES STATEMENT 1

DESCRIPTION	(A) TOTAL	(B) PROGRAM SERVICES	(C) MANAGEMENT AND GENERAL	(D) FUNDRAISING
EXECUTIVE & MANAGEMENT	80,240.		80,240.	
GENERAL OFFICE EXPENSE	1,200.		1,200.	
CREDIT CARD FEES	3,160.		3,160.	
BANK FEES	256.		256.	
WEB SITE	1,183.	1,183.		
OFFICERS & COMMITTEES	10,653.	10,653.		
CERTIFICATION, TRAINING & ACCREDITATION	1,844.	1,844.		
GOVERNMENTAL AFFAIRS	14,423.	14,423.		
BOOKKEEPING	14,673.		14,673.	
PROMOTION	333.		333.	
UROLOGY SOCIETY OF AMERICA	8,898.		8,898.	
TOTAL TO FM 990, LN 43	136,863.	28,103.	108,760.	

FORM 990 STATEMENT OF ORGANIZATION'S PRIMARY EXEMPT PURPOSE PART III STATEMENT 2

EXPLANATION

TO CONDUCT MEDICAL CONFERENCES AND DISSEMINATE INFORMATION UPDATING MEMBERS ON NEW MEDICAL PROCEDURES AND DEVELOPMENTS

11:CV-10090

HON VICTORIA ROBERTS

AMERICAN LITHOTRIPSY SOCIETY 56-1558234

FORM 990 LOANS PAYABLE TO OFFICER'S, DIRECTOR'S, ETC. STATEMENT 3

LENDER'S NAME AND TITLE	ORIGINAL LOAN AMOUNT
PHILIP MOSCA, TREASURER	5,000.

DATE OF NOTE	MATURITY DATE	TERMS OF REPAYMENT	INTEREST RATE
08/16/04	VARIOUS	SEE ATTACHED	.00%

SECURITY PROVIDED BY BORROWER	PURPOSE OF LOAN
N/A	SEE ATTACHED

DESCRIPTION OF CONSIDERATION	FMV OF CONSIDERATION	BALANCE DUE
	0.	5,000.
TOTAL TO FORM 990, PART IV, LINE 63, COLUMN B		5,000.

11:CV-10090

HON VICTORIA ROBERTS

Form **8868** (Rev. December 2004)
Department of the Treasury
Internal Revenue Service

Application for Extension of Time To File an Exempt Organization Return

▶ File a separate application for each return.

OMB No. 1545-1709

- If you are filing for an **Automatic 3-Month Extension, complete only Part I** and check this box ▶ [X]
- *If you are filing for an Additional (not automatic) 3-Month Extension, complete only Part II (on page 2 of this form).*

Do not complete Part II unless you have already been granted an automatic 3-month extension on a previously filed Form 8868.

Part I **Automatic 3-Month Extension of Time** - Only submit original (no copies needed)

Form 990-T corporations requesting an automatic 6-month extension - check this box and complete Part I only ▶ [ ]

All other corporations (including Form 990-C filers) must use Form 7004 to request an extension of time to file income tax returns. Partnerships, REMICs, and trusts must use Form 8736 to request an extension of time to file Form 1065, 1066, or 1041.

Electronic Filing (e-file). Form 8868 can be filed electronically if you want a 3-month automatic extension of time to file one of the returns noted below (6 months for corporate Form 990-T filers). However, you cannot file it electronically if you want the additional (not automatic) 3-month extension, instead you must submit the fully completed signed page 2 (Part II) of Form 8868. For more details on the electronic filing of this form, visit *www.irs.gov/efile*.

Type or print	Name of Exempt Organization	Employer identification number
File by the due date for filing your return. See instructions.	AMERICAN LITHOTRIPSY SOCIETY	56-1558234
	Number, street, and room or suite no. If a P.O. box, see instructions. 305 SECOND AVENUE, NO. 200	
	City, town or post office, state, and ZIP code. For a foreign address, see instructions. WALTHAM, MA 02451	

Check type of return to be filed (file a separate application for each return):

[X] Form 990	[ ] Form 990-T (corporation)	[ ] Form 4720
[ ] Form 990-BL	[ ] Form 990-T (sec. 401(a) or 408(a) trust)	[ ] Form 5227
[ ] Form 990-EZ	[ ] Form 990-T (trust other than above)	[ ] Form 6069
[ ] Form 990-PF	[ ] Form 1041-A	[ ] Form 8870

- The books are in the care of ▶ WESLEY E. HARRINGTON
  Telephone No. ▶ 781-895-9098 FAX No. ▶
- If the organization does not have an office or place of business in the United States, check this box ▶ [ ]
- If this is for a Group Return, enter the organization's four digit Group Exemption Number (GEN) _____. If this is for the whole group, check this box ▶ [ ]. *If it is for part of the group, check this box* ▶ [ ] *and attach a list with the names and EINs of all members the extension will cover.*

1 I request an automatic 3-month (6-months for a Form 990-T corporation) extension of time until AUGUST 15, 2005 . to file the exempt organization return for the organization named above. The extension is for the organization's return for:
▶ [X] calendar year 2004 or
▶ [ ] tax year beginning _____, and ending _____.

2 If this tax year is for less than 12 months, check reason: [ ] Initial return [ ] Final return [ ] Change in accounting period

3a If this application is for Form 990-BL, 990-PF, 990-T, 4720, or 6069, enter the tentative tax, less any nonrefundable credits. See instructions ..... $

b If this application is for Form 990-PF or 990-T, enter any refundable credits and estimated tax payments made. Include any prior year overpayment allowed as a credit ..... $

c **Balance Due.** Subtract line 3b from line 3a. Include your payment with this form, or, if required, deposit with FTD coupon or, if required, by using EFTPS (Electronic Federal Tax Payment System). See instructions ..... $ N/A

Caution. If you are going to make an electronic fund withdrawal with this Form 8868, see Form 8453-EO and Form 8879-EO for payment instructions.

423831
01-10-05

11:CV-10090

HON VICTORIA ROBERTS

000146

...or an Additional (not automatic) 3-Month Extension, complete only Part II and check this box ▶ [X]

...plete Part II if you have already been granted an automatic 3-month extension on a previously filed Form 8868.

...filing for an Automatic 3-Month Extension, complete only Part I (on page 1).

Part II **Additional (not automatic) 3-Month Extension of Time - Must file Original and One Copy.**

Type or print. File by the extended due date for filing the return. See instructions.

Name of Exempt Organization	Employer identification number
AMERICAN LITHOTRIPSY SOCIETY	56-1558234
Number, street, and room or suite no. If a P.O. box, see instructions.	For IRS use only
305 SECOND AVENUE, NO. 200	
City, town or post office, state, and ZIP code. For a foreign address, see instructions.	
WALTHAM, MA 02451	

Check type of return to be filed (File a separate application for each return):

[X] Form 990 [ ] Form 990-EZ [ ] Form 990-T (sec. 401(a) or 408(a) trust) [ ] Form 1041-A [ ] Form 5227 [ ] Form 8870
[ ] Form 990-BL [ ] Form 990-PF [ ] Form 990-T (trust other than above) [ ] Form 4720 [ ] Form 6069

STOP: Do not complete Part II if you were not already granted an automatic 3-month extension on a previously filed Form 8868.

- The books are in the care of ▶ WESLEY E. HARRINGTON
  Telephone No. ▶ 781-895-9098 FAX No. ▶
- If the organization does not have an office or place of business in the United States, check this box ▶ [ ]
- If this is for a Group Return, enter the organization's four digit Group Exemption Number (GEN) _____. If this is for the whole group, check this box ▶ [ ]. If it is for part of the group, check this box ▶ [ ] and attach a list with the names and EINs of all members the extension is for.

4 I request an additional 3-month extension of time until NOVEMBER 15, 2005.

5 For calendar year 2004, or other tax year beginning _____ and ending _____.

6 If this tax year is for less than 12 months, check reason: [ ] Initial return [ ] Final return [ ] Change in accounting period

7 State in detail why you need the extension
THIRD PARTY INFOMATION IS STILL NOT AVAILABLE. A COMPLETE AND ACCURATE RETURN CANNOT BE COMPLETED.

8a If this application is for Form 990-BL, 990-PF, 990-T, 4720, or 6069, enter the tentative tax, less any nonrefundable credits. See instructions ..... $

b If this application is for Form 990-PF, 990-T, 4720, or 6069, enter any refundable credits and estimated tax payments made. Include any prior year overpayment allowed as a credit and any amount paid previously with Form 8868 ..... $

c **Balance Due.** Subtract line 8b from line 8a. Include your payment with this form, or, if required, deposit with FTD coupon or, if required, by using EFTPS (Electronic Federal Tax Payment System). See instructions ..... $ N/A

Signature and Verification

Under penalties of perjury, I declare that I have examined this form, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete, and that I am authorized to prepare this form.

Signature ▶ Ruth P. LeGrues Title ▶ CPA Date ▶ 8/4/05

Notice to Applicant - To Be Completed by the IRS

[✓] We have approved this application. Please attach this form to the organization's return.

[ ] We have not approved this application. However, we have granted a 10-day grace period from the later of the date shown below or the due date of the organization's return (including any prior extensions). This grace period is considered to be a valid extension of time for elections otherwise required to be made on a timely return. Please attach this form to the organization's return.

[ ] We have not approved this application. After considering the reasons stated in item 7, we cannot grant your request for an extension of time to file. We are not granting a 10-day grace period.

[ ] We cannot consider this application because it was filed after the extended due date of the return for which an extension was requested.

[ ] Other _____

EXTENSION APPROVED

By: _____ Date AUG 26 2005

Director

FIELD DIRECTOR, SUBMISSION PROCESSING, OGDEN

Alternate Mailing Address - Enter the address if you want the copy of this application for an additional 3-month extension returned to an address different than the one entered above.

Type or print

Name
RUSSELL, BRIER & COMPANY, LLP

Number and street (include suite, room, or apt. no.) or a P.O. box number
TEN POST OFFICE SQUARE, 6TH FLOOR

City or town, province or state, and country (including postal or ZIP code)
BOSTON, MA 02109

423832 01-10-05

Form 8868 (Rev. 12-2004)

11:CV-10090

HON VICTORIA ROBERTS

000147

Form **990**

Department of the Treasury
Internal Revenue Service

Return of Organization Exempt From Income Tax

Under section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code (except black lung benefit trust or private foundation)

▶ The organization may have to use a copy of this return to satisfy state reporting requirements

OMB No 1545-0047

2005

Open to Public Inspection

A For the 2005 calendar year, or tax year beginning and ending

B Check if applicable:
- ☐ Address change
- ☐ Name change
- ☐ Initial return
- ☐ Final return
- ☐ Amended return
- ☐ Application pending

Please use IRS label or print or type See Specific Instructions

C Name of organization: AMERICAN LITHOTRIPSY SOCIETY

D Employer identification number: 56-1558234

Number and street (or P O box if mail is not delivered to street address): 305 SECOND AVENUE

Room/suite: 200

E Telephone number: 781-895-9098

City or town, state or country, and ZIP + 4: WALTHAM, MA 02451

F Accounting method: [X] Cash ☐ Accrual ☐ Other (specify) ▶

● Section 501(c)(3) organizations and 4947(a)(1) nonexempt charitable trusts must attach a completed Schedule A (Form 990 or 990-EZ).

H and I are not applicable to section 527 organizations.

H(a) Is this a group return for affiliates? ☐ Yes [X] No

H(b) If "Yes," enter number of affiliates ▶ N/A

H(c) Are all affiliates included? N/A ☐ Yes ☐ No (If "No," attach a list)

H(d) Is this a separate return filed by an organization covered by a group ruling? ☐ Yes [X] No

G Website: ▶WWW.LITHOTRIPSY.ORG

J Organization type (check only one) ▶ [X] 501(c) (6) ◀ (insert no) ☐ 4947(a)(1) or ☐ 527

I Group Exemption Number ▶ N/A

K Check here ▶ ☐ if the organization's gross receipts are normally not more than $25,000 The organization need not file a return with the IRS, but if the organization chooses to file a return, be sure to file a complete return. Some states require a complete return.

M Check ▶ ☐ if the organization is not required to attach Sch B (Form 990, 990-EZ, or 990-PF)

L Gross receipts Add lines 6b, 8b, 9b, and 10b to line 12 ▶ 332,213.

Part I Revenue, Expenses, and Changes in Net Assets or Fund Balances

1	Contributions, gifts, grants, and similar amounts received				
a	Direct public support	1a	119,525.		
b	Indirect public support	1b			
c	Government contributions (grants)	1c			
d	Total (add lines 1a through 1c) (cash $ 119,525. noncash $)			1d	119,525.
2	Program service revenue including government fees and contracts (from Part VII, line 93)			2	5,390.
3	Membership dues and assessments			3	1,560.
4	Interest on savings and temporary cash investments			4	3.
5	Dividends and interest from securities			5	
6 a	Gross rents	6a			
b	Less rental expenses	6b			
c	Net rental income or (loss) (subtract line 6b from line 6a)			6c	
7	Other investment income (describe ▶)			7	
8 a	Gross amount from sales of assets other than inventory — (A) Securities	8a	(B) Other		
b	Less cost or other basis and sales expenses	8b			
c	Gain or (loss) (attach schedule)	8c			
d	Net gain or (loss) (combine line 8c, columns (A) and (B))			8d	
9	Special events and activities (attach schedule) If any amount is from gaming, check here ▶ ☐				
a	Gross revenue (not including $ of contributions reported on line 1a)	9a			
b	Less direct expenses other than fundraising expenses	9b			
c	Net income or (loss) from special events (subtract line 9b from line 9a)			9c	
10 a	Gross sales of inventory, less returns and allowances	10a			
b	Less cost of goods sold	10b			
c	Gross profit or (loss) from sales of inventory (attach schedule) (subtract line 10b from line 10a)			10c	
11	Other revenue (from Part VII, line 103)			11	205,735.
12	Total revenue (add lines 1d, 2, 3, 4, 5, 6c, 7, 8d, 9c, 10c, and 11)			12	332,213.
13	Program services (from line 44, column (B))			13	115,321.
14	Management and general (from line 44, column (C))			14	77,642.
15	Fundraising (from line 44, column (D))			15	
16	Payments to affiliates (attach schedule)			16	
17	Total expenses (add lines 16 and 44, column (A))			17	192,963.
18	Excess or (deficit) for the year (subtract line 17 from line 12)			18	139,250.
19	Net assets or fund balances at beginning of year (from line 73, column (A))			19	-4,329.
20	Other changes in net assets or fund balances (attach explanation)			20	0.
21	Net assets or fund balances at end of year (combine lines 18, 19, and 20)			21	134,921.

SCANNED DEC 17 2006

RECEIVED
NOV 20 2006
OGDEN, UT
1040 IRS-OSC

523001
02-03-06 LHA For Privacy Act and Paperwork Reduction Act Notice, see the separate instructions. Form 990 (2005)

10261109 757939 300024 11:37 2005.06010 AMERICAN LITHOTRIPSY SOCIET 300024_1

HON VICTORIA ROBERTS

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Part II Statement of Functional Expenses All organizations must complete column (A). Columns (B), (C), and (D) are required for section 501(c)(3) and (4) organizations and section 4947(a)(1) nonexempt charitable trusts but optional for others

Do not include amounts reported on line 6b, 8b, 9b, 10b, or 16 of Part I.		(A) Total	(B) Program services	(C) Management and general	(D) Fundraising
22 Grants and allocations (attach schedule) (cash $ 0. noncash $ 0.) If this amount includes foreign grants, check here ▶ ☐	22				
23 Specific assistance to individuals (attach schedule)	23				
24 Benefits paid to or for members (attach schedule)	24				
25 Compensation of officers, directors, etc.	25	0.	0.	0.	0.
26 Other salaries and wages	26				
27 Pension plan contributions	27				
28 Other employee benefits	28				
29 Payroll taxes	29				
30 Professional fundraising fees	30				
31 Accounting fees	31				
32 Legal fees	32				
33 Supplies	33	261.		261.	
34 Telephone	34	5,441.		5,441.	
35 Postage and shipping	35	2,547.		2,547.	
36 Occupancy	36				
37 Equipment rental and maintenance	37				
38 Printing and publications	38	2,812.		2,812.	
39 Travel	39				
40 Conferences, conventions, and meetings	40	43,550.	43,550.		
41 Interest	41	382.		382.	
42 Depreciation, depletion, etc. (attach schedule)	42				
43 Other expenses not covered above (itemize):					
a	43a				
b	43b				
c	43c				
d	43d				
e	43e				
f	43f				
g SEE STATEMENT 1	43g	137,970.	71,771.	66,199.	
44 Total functional expenses. Add lines 22 through 43. (Organizations completing columns (B)-(D), carry these totals to lines 13-15)	44	192,963.	115,321.	77,642.	0.

Joint Costs. Check ▶ ☐ if you are following SOP 98-2.

Are any joint costs from a combined educational campaign and fundraising solicitation reported in (B) Program services? ▶ ☐ Yes ☒ No

If "Yes," enter (i) the aggregate amount of these joint costs $ N/A , (ii) the amount allocated to Program services $ N/A ,

(iii) the amount allocated to Management and general $ N/A , and (iv) the amount allocated to Fundraising $ N/A

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HON VICTORIA ROBERTS

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02-03-06

Part III Statement of Program Service Accomplishments *(See the instructions.)*

Form 990 is available for public inspection and, for some people, serves as the primary or sole source of information about a particular organization. How the public perceives an organization in such cases may be determined by the information presented on its return. Therefore, please make sure the return is complete and accurate and fully describes, in Part III, the organization's programs and accomplishments.

What is the organization's primary exempt purpose? ▶ SEE STATEMENT 2

All organizations must describe their exempt purpose achievements in a clear and concise manner. State the number of clients served, publications issued, etc. Discuss achievements that are not measurable. (Section 501(c)(3) and (4) organizations and 4947(a)(1) nonexempt charitable trusts must also enter the amount of grants and allocations to others.)

Program Service Expenses (Required for 501(c)(3) and (4) orgs., and 4947(a)(1) trusts, but optional for others.)

a ANNUAL MEETING - PROVIDE MEMBERS WITH CLINICAL PRESENTATIONS AND FORUMS FEATURING DISCUSSIONS PERTAINING TO URINARY AND BILIARY LITHOTRIPSY, LONG TERM RESULTS, AND EFFICACY OF CURRENT TECHNOLOGY.

(Grants and allocations $) If this amount includes foreign grants, check here ▶ ☐ 43,571.

b LEGAL & PROFESSIONAL FEES - FOR COSTS ASSOCIATED WITH GOVERNMENTAL AFFAIRS MONITORING ACTIVITY AND STATISTICAL RESEARCH

(Grants and allocations $) If this amount includes foreign grants, check here ▶ ☐ 70,225.

c OFFICERS AND COMMITTEES - PERIODIC MEETING TO UPDATE THE SOCIETY WITH THE LATEST MEDICAL TECHNOLOGIES.

(Grants and allocations $) If this amount includes foreign grants, check here ▶ ☐ 1,100.

d OTHER PROGRAM SERVICES RELATED TO QUALITY AND CERTIFICATION PROGRAMS OF THE SOCIETY.

(Grants and allocations $) If this amount includes foreign grants, check here ▶ ☐ 425.

e Other program services (attach schedule)

(Grants and allocations $) If this amount includes foreign grants, check here ▶ ☐

f **Total of Program Service Expenses** (should equal line 44, column (B), Program services) ▶ 115,321.

Form **990** (2005)

11:CV-10090

HON VICTORIA ROBERTS

523021
02-03-06

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Part IV Balance Sheets *(See the instructions.)*

	Note: *Where required, attached schedules and amounts within the description column should be for end-of-year amounts only.*			(A) Beginning of year		(B) End of year
Assets	45 Cash - non-interest-bearing			123.	45	449.
	46 Savings and temporary cash investments			548.	46	467.
	47 a Accounts receivable	47a				
	b Less: allowance for doubtful accounts	47b			47c	
	48 a Pledges receivable	48a				
	b Less: allowance for doubtful accounts	48b			48c	
	49 Grants receivable				49	
	50 Receivables from officers, directors, trustees, and key employees				50	
	51 a Other notes and loans receivable	51a	135,184.			
	b Less: allowance for doubtful accounts	51b			51c	135,184.
	52 Inventories for sale or use				52	
	53 Prepaid expenses and deferred charges				53	2,336.
	54 Investments - securities ▶ ☐ Cost ☐ FMV				54	
	55 a Investments - land, buildings, and equipment: basis	55a				
	b Less: accumulated depreciation	55b			55c	
	56 Investments - other				56	
	57 a Land, buildings, and equipment: basis	57a				
	b Less: accumulated depreciation	57b			57c	
	58 Other assets (describe ▶)				58	
	59 **Total assets** (must equal line 74). Add lines 45 through 58			671.	59	138,436.
Liabilities	60 Accounts payable and accrued expenses				60	
	61 Grants payable				61	
	62 Deferred revenue				62	
	63 Loans from officers, directors, trustees, and key employees STMT 3			5,000.	63	3,515.
	64 a Tax-exempt bond liabilities				64a	
	b Mortgages and other notes payable				64b	
	65 Other liabilities (describe ▶)				65	
	66 **Total liabilities.** Add lines 60 through 65)			5,000.	66	3,515.
Net Assets or Fund Balances	**Organizations that follow SFAS 117, check here** ▶ ☒ and complete lines 67 through 69 and lines 73 and 74.					
	67 Unrestricted			-21,583.	67	68,367.
	68 Temporarily restricted			17,254.	68	66,554.
	69 Permanently restricted				69	
	Organizations that do not follow SFAS 117, check here ▶ ☐ and complete lines 70 through 74.					
	70 Capital stock, trust principal, or current funds				70	
	71 Paid-in or capital surplus, or land, building, and equipment fund				71	
	72 Retained earnings, endowment, accumulated income, or other funds				72	
	73 **Total net assets or fund balances** (add lines 67 through 69 or lines 70 through 72, column (A) must equal line 19, column (B) must equal line 21)			-4,329.	73	134,921.
	74 **Total liabilities and net assets/fund balances.** Add lines 66 and 73			671.	74	138,436.

11:CV-10090

HON VICTORIA ROBERTS

523031
02-03-06

Part IV-A Reconciliation of Revenue per Audited Financial Statements With Revenue per Return *(See the instructions.)*

a	Total revenue, gains, and other support per audited financial statements		a	N/A
b	Amounts included on line a but not on Part I, line 12:			
1	Net unrealized gains on investments	b1		
2	Donated services and use of facilities	b2		
3	Recoveries of prior year grants	b3		
4	Other (specify):	b4		
	Add lines b1 through b4		b	
c	Subtract line b from line a		c	
d	Amounts included on Part I, line 12, but not on line a:			
1	Investment expenses not included on Part I, line 6b	d1		
2	Other (specify):	d2		
	Add lines d1 and d2		d	
e	Total revenue (Part I, line 12). Add lines c and d	▶	e	

Part IV-B Reconciliation of Expenses per Audited Financial Statements With Expenses per Return

a	Total expenses and losses per audited financial statements		a	N/A
b	Amounts included on line a but not on Part I, line 17:			
1	Donated services and use of facilities	b1		
2	Prior year adjustments reported on Part I, line 20	b2		
3	Losses reported on Part I, line 20	b3		
4	Other (specify):	b4		
	Add lines b1 through b4		b	
c	Subtract line b from line a		c	
d	Amounts included on Part I, line 17, but not on line a:			
1	Investment expenses not included on Part I, line 6b	d1		
2	Other (specify):	d2		
	Add lines d1 and d2		d	
e	Total expenses (Part I, line 17). Add lines c and d	▶	e	

Part V-A Current Officers, Directors, Trustees, and Key Employees (List each person who was an officer, director, trustee, or key employee at any time during the year even if they were not compensated.) *(See the instructions.)*

(A) Name and address	(B) Title and average hours per week devoted to position	(C) Compensation (If not paid, enter -0-.)	(D) Contributions to employee benefit plans & deferred compensation plans	(E) Expense account and other allowances
SEE STATEMENT 4		0.	0.	0.
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HON VICTORIA ROBERTS

Part V-A Current Officers, Directors, Trustees, and Key Employees *(continued)*

			Yes	No
75 a	Enter the total number of officers, directors, and trustees permitted to vote on organization business at board meetings ▶ 11			
b	Are any officers, directors, trustees, or key employees listed in Form 990, Part V-A, or highest compensated employees listed in Schedule A, Part I, or highest compensated professional and other independent contractors listed in Schedule A, Part II-A or II-B, related to each other through family or business relationships? If "Yes," attach a statement that identifies the individuals and explains the relationship(s)	75b		X
c	Do any officers, directors, trustees, or key employees listed in Form 990, Part V-A, or highest compensated employees listed in Schedule A, Part I, or highest compensated professional and other independent contractors listed in Schedule A, Part II-A or II-B, receive compensation from any other organizations, whether tax exempt or taxable, that are related to this organization through common supervision or common control?	75c		X
	Note. Related organizations include section 509(a)(3) supporting organizations. If "Yes," attach a statement that identifies the individuals, explains the relationship between this organization and the other organization(s), and describes the compensation arrangements, including amounts paid to each individual by each related organization.			
d	Does the organization have a written conflict of interest policy?	75d	X	

Part V-B Former Officers, Directors, Trustees, and Key Employees That Received Compensation or Other Benefits (If any former officer, director, trustee, or key employee received compensation or other benefits (described below) during the year, list that person below and enter the amount of compensation or other benefits in the appropriate column. See the instructions.)

(A) Name and address	(B) Loans and Advances	(C) Compensation	(D) Contributions to employee benefit plans & deferred compensation plans	(E) Expense account and other allowances
NONE				

Part VI Other Information *(See the instructions.)*

			Yes	No
76	Did the organization engage in any activity not previously reported to the IRS? If "Yes," attach a detailed description of each activity	76		X
77	Were any changes made in the organizing or governing documents but not reported to the IRS? If "Yes," attach a conformed copy of the changes.	77		X
78 a	Did the organization have unrelated business gross income of $1,000 or more during the year covered by this return?	78a		X
b	If "Yes," has it filed a tax return on Form 990-T for this year? N/A	78b		
79	Was there a liquidation, dissolution, termination, or substantial contraction during the year? If "Yes," attach a statement	79		X
80 a	Is the organization related (other than by association with a statewide or nationwide organization) through common membership, governing bodies, trustees, officers, etc., to any other exempt or nonexempt organization?	80a	X	
b	If "Yes," enter the name of the organization ▶ UROLOGY SOCIETY OF AMERICA and check whether it is [X] exempt or [ ] nonexempt			
81 a	Enter direct or indirect political expenditures. (See line 81 instructions.) 81a 0.			
b	Did the organization file Form 1120-POL for this year?	81b		X

Part VI Other Information *(continued)*

			Yes	No
82 a	Did the organization receive donated services or the use of materials, equipment, or facilities at no charge or at substantially less than fair rental value?	82a	X	
b	If "Yes," you may indicate the value of these items here. Do not include this amount as revenue in Part I or as an expense in Part II. (See instructions in Part III.) 82b			
83 a	Did the organization comply with the public inspection requirements for returns and exemption applications?	83a	X	
b	Did the organization comply with the disclosure requirements relating to quid pro quo contributions?	83b	X	
84 a	Did the organization solicit any contributions or gifts that were not tax deductible?	84a		X
b	If "Yes," did the organization include with every solicitation an express statement that such contributions or gifts were not tax deductible? N/A	84b		
85	*501(c)(4), (5), or (6) organizations.* a Were substantially all dues nondeductible by members?	85a		X
b	Did the organization make only in-house lobbying expenditures of $2,000 or less?	85b	X	
	If "Yes" was answered to either 85a or 85b, do not complete 85c through 85h below unless the organization received a waiver for proxy tax owed for the prior year.			
c	Dues, assessments, and similar amounts from members 85c N/A			
d	Section 162(e) lobbying and political expenditures 85d N/A			
e	Aggregate nondeductible amount of section 6033(e)(1)(A) dues notices 85e N/A			
f	Taxable amount of lobbying and political expenditures (line 85d less 85e) 85f N/A			
g	Does the organization elect to pay the section 6033(e) tax on the amount on line 85f? N/A	85g		
h	If section 6033(e)(1)(A) dues notices were sent, does the organization agree to add the amount on line 85f to its reasonable estimate of dues allocable to nondeductible lobbying and political expenditures for the following tax year? N/A	85h		
86	*501(c)(7) organizations.* Enter: a Initiation fees and capital contributions included on line 12 86a N/A			
b	Gross receipts, included on line 12, for public use of club facilities 86b N/A			
87	*501(c)(12) organizations.* Enter: a Gross income from members or shareholders 87a N/A			
b	Gross income from other sources. (Do not net amounts due or paid to other sources against amounts due or received from them.) 87b N/A			
88	At any time during the year, did the organization own a 50% or greater interest in a taxable corporation or partnership, or an entity disregarded as separate from the organization under Regulations sections 301.7701-2 and 301.7701-3? If "Yes," complete Part IX	88		X
89 a	*501(c)(3) organizations.* Enter: Amount of tax imposed on the organization during the year under: section 4911 ▶ N/A, section 4912 ▶ N/A, section 4955 ▶ N/A			
b	*501(c)(3) and 501(c)(4) organizations.* Did the organization engage in any section 4958 excess benefit transaction during the year or did it become aware of an excess benefit transaction from a prior year? If "Yes," attach a statement explaining each transaction N/A	89b		
c	Enter: Amount of tax imposed on the organization managers or disqualified persons during the year under sections 4912, 4955, and 4958 ▶ N/A			
d	Enter: Amount of tax on line 89c, above, reimbursed by the organization ▶ N/A			
90 a	List the states with which a copy of this return is filed ▶ NC			
b	Number of employees employed in the pay period that includes March 12, 2005 90b 0			
91 a	The books are in care of ▶ WESLEY E. HARRINGTON Telephone no ▶ 781-895-9098 Located at ▶ 305 SECOND AVE, SUITE 200, WALTHAM, MA ZIP + 4 ▶ 02451			
b	At any time during the calendar year, did the organization have an interest in or a signature or other authority over a financial account in a foreign country (such as a bank account, securities account, or other financial account)? If "Yes," enter the name of the foreign country ▶ N/A See the instructions for exceptions and filing requirements for Form TD F 90-22.1, Report of Foreign Bank and Financial Accounts	91b		X
c	At any time during the calendar year, did the organization maintain an office outside of the United States? If "Yes," enter the name of the foreign country ▶ N/A	91c		X
92	*Section 4947(a)(1) nonexempt charitable trusts filing Form 990 in lieu of* Form 1041- Check here ▶ ☐ and enter the amount of tax-exempt interest received or accrued during the tax year ▶ 92 N/A			

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Part VII Analysis of Income-Producing Activities *(See the instructions.)*

Note: *Enter gross amounts unless otherwise indicated.*	Unrelated business income (A) Business code	Unrelated business income (B) Amount	Excluded by section 512, 513, or 514 (C) Exclusion code	Excluded by section 512, 513, or 514 (D) Amount	(E) Related or exempt function income
93 Program service revenue:					
a PROGRAM REVENUE					5,105.
b TRAINING					285.
c					
d					
e					
f Medicare/Medicaid payments					
g Fees and contracts from government agencies					
94 Membership dues and assessments					1,560.
95 Interest on savings and temporary cash investments			14	3.	
96 Dividends and interest from securities					
97 Net rental income or (loss) from real estate:					
a debt-financed property					
b not debt-financed property					
98 Net rental income or (loss) from personal property					
99 Other investment income					
100 Gain or (loss) from sales of assets other than inventory					
101 Net income or (loss) from special events					
102 Gross profit or (loss) from sales of inventory					
103 Other revenue:					
a AFFILATED ORGANIZATION			01	205,735.	
b					
c					
d					
e					
104 Subtotal (add columns (B), (D), and (E))		0.		205,738.	6,950.
105 Total (add line 104, columns (B), (D), and (E))				▶	212,688.

Note: *Line 105 plus line 1d, Part I, should equal the amount on line 12, Part I.*

Part VIII Relationship of Activities to the Accomplishment of Exempt Purposes *(See the instructions.)*

Line No. ▼	Explain how each activity for which income is reported in column (E) of Part VII contributed importantly to the accomplishment of the organization's exempt purposes (other than by providing funds for such purposes)
93A &B	TO REVIEW PROCEDURES AND EQUIPMENT AT SITE LOCATIONS AND TO CERTIFY PERSONNEL AND MEMBERS.
94	DUES AND ASSESSMENTS ARE USED TO SUPPLEMENT THE ANNUAL MEETING AND SERVICE EXPENSES.

Part IX Information Regarding Taxable Subsidiaries and Disregarded Entities *(See the instructions.)*

(A) Name, address, and EIN of corporation, partnership, or disregarded entity	(B) Percentage of ownership interest	(C) Nature of activities	(D) Total income	(E) End-of-year assets
	%			
N/A	%			
	%			
	%			

Part X Information Regarding Transfers Associated with Personal Benefit Contracts *(See the instructions.)*

(a) Did the organization, during the year, receive any funds, directly or indirectly, to pay premiums on a personal benefit contract? ☐ Yes ☒ No

(b) Did the organization, during the year, pay premiums, directly or indirectly, on a personal benefit contract? ☐ Yes ☒ No

Note: *If "Yes" to (b), file Form 8870 and Form 4720 (see instructions).*

Please Sign Here — Under penalties of perjury, I declare that I have examined this return, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete. Declaration of preparer (other than officer) is based on all information of which preparer has any knowledge.

Signature of officer — Date 11/14/06 — Type or print name and title PRES/CEO

Paid Preparer's Use Only — Preparer's signature Keith P. LaGuire CPA — Date 11/8/06 — Check if self-employed ▶ ☐ — Preparer's SSN or PTIN P00068702

Firm's name (or yours if self-employed), address, and ZIP + 4 ▶ RUSSELL, BRIER & COMPANY, LLP
TEN POST OFFICE SQUARE, 6TH FLOOR
BOSTON, MA 02109-4689

EIN ▶

Phone no ▶ 617-523-7094

523163 02-03-06

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HON VICTORIA ROBERTS

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AMERICAN LITHOTRIPSY SOCIETY
305 Second Avenue, Suite 200
Waltham, Massachusetts 02451

MEMORANDUM

TO: ALS Accounting Department

CC: Dr. Philip Mosca, Ph.D., M.D.

FROM: Wesley E. Harrington, CAE
Executive Director

DATE: Monday, August 16, 2004

SUBJECT: Loan to Society from Clinical Urology, Inc. / Dr. Philip Mosca

This will confirm that on Friday, August 15, 2004, the American Lithotripsy Society (ALS) received a credit card remittance from Clinical Urology, Inc. / Dr. Philip Mosca in the amount of $5,000 to serve as a loan to the Society, and to be used to provide 50% of a good faith payment to the Manchester Grand Hyatt Hotel in San Diego, California as partial settlement for expenses related to the operation of the 2004 ALS/USA Annual Meeting at that facility. These funds were deposited in Eastern Bank on Sunday, August 15, 2004 in the Night Deposit Vault: it is expected that this transaction will be recorded by Eastern Bank on Monday, August 16, 2004.

This is a no-recourse loan to the Society with the following understanding:

1. The loan may be treated as an informal "debit" account in the future, whereby the costs associated with the acquisition of future services from the Society by the Urologic Institute of New Orleans / Dr. Joseph N. Macaluso shall be used to draw down the amount of funds owed to the Urologic Institute. For example, membership dues for 2005 for either ALS or USA (as a result of the merger of the two groups) will be subtracted from the amount due on this account.

2. The Executive Committee of the Society, at the recommendation of the ALS or USA Treasurer, may, at a future time when funds have stabilized for the organization, determine to remit the remaining balance to the Clinical Urology, Inc. / Dr. Philip Mosca upon petition.

AMERICAN LITHOTRIPSY SOCIETY 56-1558234

FORM 990 OTHER EXPENSES STATEMENT 1

DESCRIPTION	(A) TOTAL	(B) PROGRAM SERVICES	(C) MANAGEMENT AND GENERAL	(D) FUNDRAISING
BOOKKEEPING	7,063.		7,063.	
WEBSITE EXPENSE	4,093.		4,093.	
GENERAL OFFICE EXPENSES	800.		800.	
CREDIT CARD PROC FEES	3,963.		3,963.	
MANAGEMENT FEES	50,280.		50,280.	
PROGRAM EXPENSE	425.	425.		
BOARD OF DIRECTORS	354.	354.		
PROGRAM COMMITTEE	767.	767.		
GOVERNMENT AFFAIRS	70,225.	70,225.		
TOTAL TO FM 990, LN 43	137,970.	71,771.	66,199.	

FORM 990 STATEMENT OF ORGANIZATION'S PRIMARY EXEMPT PURPOSE PART III STATEMENT 2

EXPLANATION

TO CONDUCT MEDICAL CONFERENCES AND DISSEMINATE INFORMATION UPDATING MEMBERS ON NEW MEDICAL PROCEDURES AND DEVELOPMENTS

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HON VICTORIA ROBERTS

AMERICAN LITHOTRIPSY SOCIETY 56-1558234

FORM 990 LOANS PAYABLE TO OFFICER'S, DIRECTOR'S, ETC. STATEMENT 3

LENDER'S NAME AND TITLE	ORIGINAL LOAN AMOUNT
PHILIP MOSCA, PRESIDENT	5,000.

DATE OF NOTE	MATURITY DATE	TERMS OF REPAYMENT	INTEREST RATE
08/16/04	VARIOUS	SEE ATTACHED	.00%

SECURITY PROVIDED BY BORROWER	PURPOSE OF LOAN
N/A	SEE ATTACHED

DESCRIPTION OF CONSIDERATION	FMV OF CONSIDERATION	BALANCE DUE
	0.	3,515.
TOTAL TO FORM 990, PART IV, LINE 63, COLUMN B		3,515.

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AMERICAN LITHOTRIPSY SOCIETY 56-1558234

FORM 990 PART V-A - LIST OF OFFICERS, DIRECTORS, TRUSTEES AND KEY EMPLOYEES STATEMENT 4

NAME AND ADDRESS	TITLE AND AVRG HRS/WK	COMPEN-SATION	EMPLOYEE BEN PLAN CONTRIB	EXPENSE ACCOUNT
PHILIP MOSCA, PH.D.,M.D. 305 SECOND AVENUE WALTHAM, MA 02451	PRESIDENT 2.00	0.	0.	0.
ROBERT KAHN, MD 305 SECOND AVENUE WALTHAM, MA 02451	PRESIDENT-ELECT 2.00	0.	0.	0.
THAYNE LARSON, MD 305 SECOND AVENUE WALTHAM, MA 02451	SECRETARY-TREASURER 2.00	0.	0.	0.
CONNIE KARLOFF, RN, CRLS 305 SECOND AVENUE WALTHAM, MA 02451	PRESIDENT-ALLIED SECTION 2.00	0.	0.	0.
DANIEL JOHNSON, MD 305 SECOND AVENUE WALTHAM, MA 02451	CHAIR-MEMBERSHIP/MARKETING 2.00	0.	0.	0.
RICHARD KRANZ, RT, CRLS 305 SECOND AVENUE WALTHAM, MA 02451	CHAIR-MEMBERSHIP/MARKETING 2.00	0.	0.	0.
JOSEPH MACALUSO, JR, MD 305 SECOND AVENUE WALTHAM, MA 02451	CHAIR-PROGRAM 2.00	0.	0.	0.
MARIE LEE, RN 305 SECOND AVENUE WALTHAM, MA 02451	CHAIR-PROGRAM 2.00	0.	0.	0.
MICHAEL DERNOGO 305 SECOND AVENUE WALTHAM, MA 02451	CHAIR-GOVERNMENT AFFAIRS 2.00	0.	0.	0.
THOMAS MAWN, MD 305 SECOND AVENUE WALTHAM, MA 02451	CHAIR-ACCREDITATION 2.00	0.	0.	0.
PAUL W. F. COUGHLIN 305 SECOND AVENUE WALTHAM, MA 02451	IMMEDIATE PAST PRESIDENT 2.00	0.	0.	0.
TOTALS INCLUDED ON FORM 990, PART V-A		0.	0.	0.

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HON VICTORIA ROBERTS

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- If you are filing for an **Additional (not automatic) 3-Month Extension, complete only Part II** and check this box . . . . . ▶ [X]

Note: Only complete Part II if you have already been granted an automatic 3-month extension on a previously filed Form 8868.

- If you are filing for an **Automatic 3-Month Extension, complete only Part I** (on page 1).

Part II Additional (not automatic) 3-Month Extension of Time - Must file Original and One Copy.

Type or print. File by the extended due date for filing the return. See instructions.	Name of Exempt Organization		Employer identification number
	AMERICAN LITHOTRIPSY SOCIETY		56-1558234
	Number, street, and room or suite no. If a P.O. box, see instructions.		For IRS use only
	305 SECOND AVENUE, NO. 200		
	City, town or post office, state, and ZIP code. For a foreign address, see instructions.		
	WALTHAM, MA 02451		

Check type of return to be filed (File a separate application for each return):

[X] Form 990 [ ] Form 990-EZ [ ] Form 990-T (sec. 401(a) or 408(a) trust) [ ] Form 1041-A [ ] Form 5227 [ ] Form 8870
[ ] Form 990-BL [ ] Form 990-PF [ ] Form 990-T (trust other than above) [ ] Form 4720 [ ] Form 6069

STOP: Do not complete Part II if you were not already granted an automatic 3-month extension on a previously filed Form 8868.

- The books are in the care of ▶ WESLEY E. HARRINGTON
  Telephone No. ▶ 781-895-9098 FAX No. ▶
- If the organization does not have an office or place of business in the United States, check this box . . . . . ▶ [ ]
- If this is for a Group Return, enter the organization's four digit Group Exemption Number (GEN) _____. If this is for the whole group, check this box ▶ [ ]. If it is for part of the group, check this box ▶ [ ] and attach a list with the names and EINs of all members the extension is for.

4 I request an additional 3-month extension of time until NOVEMBER 15, 2006.

5 For calendar year 2005, or other tax year beginning _____ and ending _____.

6 If this tax year is for less than 12 months, check reason: [ ] Initial return [ ] Final return [ ] Change in accounting period

7 State in detail why you need the extension
THIRD PARTY INFORMATION HAS NOT YET BEEN RECEIVED.
ADDITIONAL TIME IS REQUIRED TO PREPARE A COMPLETE AND ACCURATE RETURN.

8a If this application is for Form 990-BL, 990-PF, 990-T, 4720, or 6069, enter the tentative tax, less any nonrefundable credits. See instructions . . . . . $

b If this application is for Form 990-PF, 990-T, 4720, or 6069, enter any refundable credits and estimated tax payments made. Include any prior year overpayment allowed as a credit and any amount paid previously with Form 8868 . . . . . $

c **Balance Due.** Subtract line 8b from line 8a. Include your payment with this form, or, if required, deposit with FTD coupon or, if required, by using EFTPS (Electronic Federal Tax Payment System). See instructions $ N/A

Signature and Verification

Under penalties of perjury, I declare that I have examined this form, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete, and that I am authorized to prepare this form

Signature ▶ Keith P. La Grenas Title ▶ CPA Date ▶ 8-11-06

Notice to Applicant - To Be Completed by the IRS

[ ] We have approved this application. Please attach this form to the organization's return.

[ ] We have not approved this application. However, we have granted a 10-day grace period from the later of the date shown below or the due date of the organization's return (including any prior extensions). This grace period is considered to be a valid extension of time for elections otherwise required to be made on a timely return. Please attach this form to the organization's return.

[ ] We have not approved this application. After considering the reasons stated in item 7, we cannot grant your request for an extension of time to file. We are not granting a 10-day grace period.

[ ] We cannot consider this application because it was filed after the extended due date of the return for which an extension was requested.

[ ] Other _____

_____ By _____ _____
Director Date

Alternate Mailing Address - Enter the address if you want the copy of this application for an additional 3-month extension returned to an address different than the one entered above.

Type or print	Name
	Number and street (include suite, room, or apt. no.) or a P.O. box number
	City or town, province or state, and country (including postal or ZIP code)

523832 05-01-05

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HON VICTORIA ROBERTS

American Kidney Stone Management

- Summary
- Recipients
- Donors
- Expenditures
- PAC to PAC/Party

Select a Cycle: 2012

House

Total to Democrats: $0
Total to Republicans: $253,000

Recipient	Total
Boehner, John (R-OH)	$5,000
Buchanan, Vernon (R-FL)	$7,000
Burgess, Michael (R-TX)	$10,000
Camp, Dave (R-MI)	$6,000
Campbell, John (R-CA)	$1,000
Cantor, Eric (R-VA)	$6,000
Cassidy, Bill (R-LA)	$6,000
Cotton, Tom (R-AR)	$10,000
Gardner, Cory (R-CO)	$6,000
Gingrey, Phil (R-GA)	$7,500
Goodlatte, Bob (R-VA)	$10,000
Gosar, Paul (R-AZ)	$7,000
Griffin, Tim (R-AR)	$10,000
Guthrie, Brett (R-KY)	$1,000
Heck, Joe (R-NV)	$10,000
Hensarling, Jeb (R-TX)	$6,000
Huizenga, Bill (R-MI)	$1,000
Johnson, Sam (R-TX)	$6,000
Marino, Tom (R-PA)	$10,000
McCarthy, Kevin (R-CA)	$6,000
McKinley, David (R-WV)	$7,000
Murphy, Tim (R-PA)	$4,500
Nugent, Richard (R-FL)	$7,000
Pitts, Joe (R-PA)	$10,000
Price, Tom (R-GA)	$10,000

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HON VICTORIA ROBERTS

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Recipient	Total
Quayle, Ben (R-AZ)	$5,000
Roskam, Peter (R-IL)	$10,000
Runyan, Jon (R-NJ)	$10,000
Schock, Aaron (R-IL)	$8,500
Schweikert, David (R-AZ)	$3,500
Sessions, Pete (R-TX)	$8,000
Stearns, Cliff (R-FL)	$7,500
Stivers, Steve (R-OH)	$10,000
Tiberi, Patrick J (R-OH)	$10,000
Turner, Michael R (R-OH)	$7,000
Upton, Fred (R-MI)	$3,500

Senate

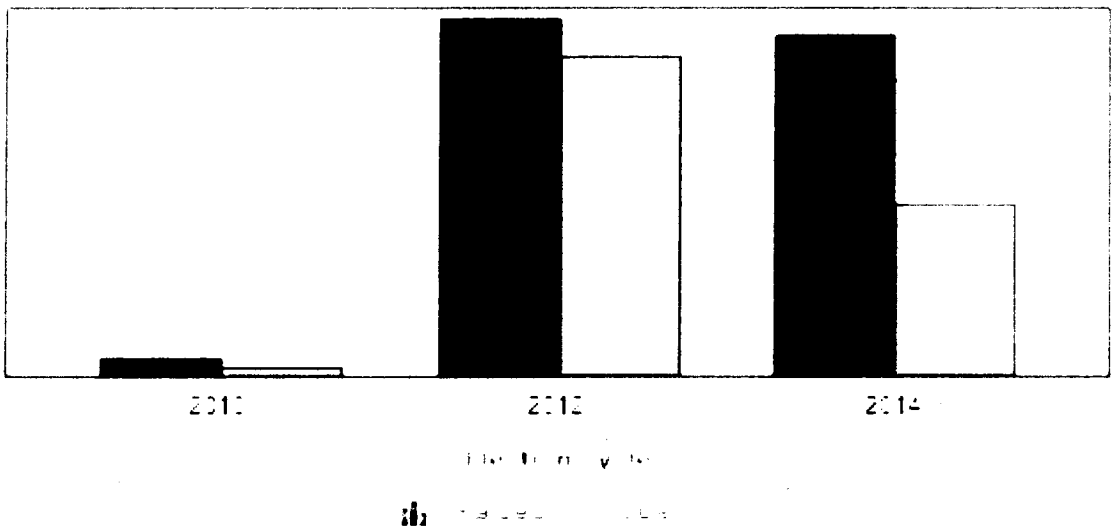
Total to Democrats: $6,000
Total to Republicans: $18,000

Recipient	Total
Boozman, John (R-AR)	$2,000
Flake, Jeff (R-AZ)	$6,000
Mandel, Josh (R-OH)	$5,000
Snowe, Olympia (R-ME)	$5,000
Stabenow, Debbie (D-MI)	$6,000

Based on data released by the FEC on March 25, 2013.

Search for a PAC Enter at least 3 characters

American Kidney Stone Management



2012 PAC Summary Data

Select a Cycle: 2012

Total Receipts	$388,461
Total Spent	$347,799
Begin Cash on Hand	$8,927
End Cash on Hand	$49,589
Debts	$658
Date of last report	December 31, 2012

2012 PAC Contribution Data

Contributions from *this PAC to federal candidates* ( ) (2% to Democrats, 98% to Republicans)	$277,000
Contributions to *this PAC from individual donors of $200 or more* ( )	$268,110

Official PAC Name:
AKSM UROLOGY POLITICAL ACTION COMMITTEE 'AKSM UROLOGY PAC'
Location: COLUMBUS, OH 43201
Industry: Outpatient health services (incl drug & alcohol)

Treasurer: HUGHES, RIC
FEC Committee ID: C00489419
(Look up at the FEC)

Search for a PAC

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HON VICTORIA ROBERTS

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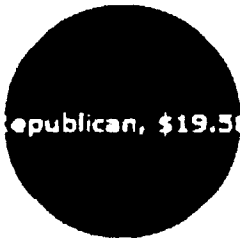
American Kidney Stone Management

Select a Cycle: 2012

Party Breakdown



Contributions from this PAC	Total
DOC PAC (Affiliate: Phil Gingrey (R-Ga))	$7,500
Freedom Project (Affiliate: John Boehner (R-Ohio))	$5,000
Diamond PAC (Affiliate: Tim Griffin (R-Ark))	$5,000
Snowe, Olympia	$2,000

Search for a PAC

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HON VICTORIA ROBERTS

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American Kidney Stone Management

Election cycle: 2012

Administrative	Miscellaneous administrative	$23,693
	Accountants, compliance & legal services	$18,818
Contributions	Contributions to federal candidates	$276,000
	Contributions to committees	$17,500
Salaries	Salaries, wages & benefits	$2,852

Top Vendors/Recipients

1	American Kidney Stone Management, Ltd	$19,634
2	Squire Sanders (Us)	$14,924
3	Friends Of Joe Heck	$10,000
3	David Price for Congress	$10,000
3	John Runyan for Congress	$10,000
3	Stivers For Congress	$10,000
3	Bob Goodlatte For Congress Cmte	$10,000
3	Michael Burgess For Congress	$10,000
3	Cotton For Congress	$10,000

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3	Marino For Congress	$10,000
3	Tim Griffin for Congress	$10,000
3	Roskam for Congress	$10,000
3	Tiberi For Congress	$10,000

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HON VICTORIA ROBERTS

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American Kidney Stone Management

- Summary
- Recipients
- Donors
- Expenditures
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Select a Cycle: 2012

Individual donors gave 992 large ($200+) contributions to this PAC in 2011-2012.

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Contrib	Occupation	Date	Amount
LO, HAN P SAN JOSE, CA 95112	UROLOGIST SURGEONS OF N. CA./UROLOG	11/18/11	$1,000
PANVINI, ROBERT P SAN JOSE, CA 95124	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
GHOLAMI, SHAHRAM S MONTE SORRENO, CA 95030	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
HWONG, LAWRENCE Y SAN JOSE, CA 95112	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
KARPMAN, EDWARD MOUNTAIN VIEW, CA 94040	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
KING, DAVID HC LOS GATOS, CA 95033	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
WHERRY, PATRICK SAN JOSE, CA 95124	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
LEVESQUE, PETER NORTH EASTON, MA 02356	TAUNTON UROLOGIC ASSOCIATES/UROLOGI	11/03/11	$1,000
LEVINE, SARI R LOS ALTOS, CA 94024	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
NOLLER, DAVID W SAN JOSE, CA 95120	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
NUDELL, DAVID MARK LOS ALTOS, CA 94022	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
KONG, WESLEY GN PALO ALTO, CA 94303	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
KRAFT, JOHN KERSTEN SARATOGA, CA 95070	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
SULLIVAN, TERRY SAN JOSE, CA 95128	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
LAI, FRANK LOS ALTOS, CA 94024	UROLOGICAL SURGEONS OF N. CA./UROLO	11/18/11	$1,000
SAUER, DIETER GREENSBURG, PA 15601	DIETER SAUER MD INC.	05/06/11	$510
CLAYBROOK, KEVIN LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	07/13/12	$500

COUSSENS, DAVID LITTLE ROCK, AR 72211	ARKANSAS UROLOGY	07/13/12	$500
DIAZ, EDWIN LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	07/13/12	$500
VANWYCK, KRISTEN NEWAYGO, MI 49337	NEWAYGO COUNTY/LEGAL SECRETARY	10/31/11	$500
BOZEMAN, CALEB LITTLE ROCK, AR 72227	ARKANSAS UROLOGY	07/13/12	$500
BRIZZOLARA, JOHN LITTLE ROCK, AR 72107	ARKANSAS UROLOGY	07/13/12	$500
GOODSON, TIMOTHY LITTLE ROCK, AR 72207	ARKANSAS UROLOGY	07/13/12	$500
JACKS, DAVID C PINE BLUFF, AR 71603	PHYSICIAN	07/13/12	$500
JONES, GAIL REEDE LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	07/13/12	$500
KUHN, RON G ROLAND, AR 72135	ARKANSAS UROLOGY	07/13/12	$500
LANGFORD, TIM D LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	07/13/12	$500
STALLINGS, J WALT LITTLE ROCK, AR 72211	ARKANSAS UROLOGY	07/13/12	$500
VANWYCK, KRISTEN NEWAYGO, MI 49337	NEWAYGO COUNTY	01/25/11	$500
VANWYCK, KRISTEN NEWAYGO, MI 49337	NEWAYGO COUNTY	04/12/11	$500
BOZEMAN, CALEB LITTLE ROCK, AR 72227	ARKANSAS UROLOGY	10/16/12	$500
BRIZZOLARA, JOHN LITTLE ROCK, AR 72107	ARKANSAS UROLOGY	10/16/12	$500
CLAYBROOK, KEVIN LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	10/16/12	$500
COUSSENS, DAVID LITTLE ROCK, AR 72211	ARKANSAS UROLOGY	10/16/12	$500
DIAZ, EDWIN LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	10/16/12	$500
MOONEY, D KEITH LITTLE ROCK, AR 72212	ARKANSAS UROLOGY	07/13/12	$500
GOODSON, TIMOTHY LITTLE ROCK, AR 72207	ARKANSAS UROLOGY	10/16/12	$500
JACKS, DAVID C PINE BLUFF, AR 71603	PHYSICIAN	10/16/12	$500
JONES, GAIL REEDE LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	10/16/12	$500
KUHN, RON G ROLAND, AR 72135	ARKANSAS UROLOGY	10/16/12	$500
LANGFORD, TIM D LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	10/16/12	$500
MOONEY, D KEITH LITTLE ROCK, AR 72212	ARKANSAS UROLOGY	10/16/12	$500
11-CV-10090	ARKANSAS UROLOGY	10/16/12	$500

HON VICTORIA ROBERTS

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STALLINGS, J WALT LITTLE ROCK, AR 72211			
LIFSON, BARRY WILLIAMSTOWN, WV 26187	MID OHIO VALLEY MEDICAL GROUP	04/12/11	$500
LEVESQUE, PETER NORTH EASTON, MA 02356	TAUNTON UROLOGIC ASSOCIATES	12/18/12	$500
BRITO, C GILBERTO PARADISE VALLEY, AZ 85253	AUS	10/30/12	$500
MATTHEWS, PETER MESA, AZ 85213	MESA UROLOGY	10/30/12	$500
MARMER, MICHAEL PAYSON, AZ 85541	ALPINE COUNTRY UROLOGIC ASSOC.	10/30/12	$500
HOMAYOON, KAVEH PHOENIX, AZ 85054	DISTRICT MEDICAL GROUP	10/30/12	$500
SHAHON, ROBERT MESA, AZ 85202	DESERT UROLOGY CONSULTANTS	10/30/12	$500
MATTHEWS, PETER MESA, AZ 85213	MESA UROLOGY/UROLOGIST	08/02/11	$275
MATTHEWS, PETER MESA, AZ 85213	MESA UROLOGY/UROLOGIST	10/18/11	$275
MATTHEWS, PETER MESA, AZ 85213	MESA UROLOGY	02/03/11	$275
MATTHEWS, PETER MESA, AZ 85213	MESA UROLOGY	04/26/11	$275
MAYS, SPYRIE D BATON ROUGE, LA 70806	SPYRIE D. MAYS MC, FACS	06/11/11	$250
MCDEVITT, WILLIAM LAKE ORION, MI 48362	OAKLAND COUNTY UROLOGISTS	04/12/11	$250
MENDOZA, DAVID PARKERSBURG, WV 26104	MID OHIO VALLEY MEDICAL GROUP	04/12/11	$250
MERTZ, THOMAS ROSEVILLE, MI 48066	GROSSE POINTE UROLOGY	01/25/11	$250
MERTZ, THOMAS ROSEVILLE, MI 48066	GROSSE POINTE UROLOGY	04/12/11	$250
MONSOUR, JILL SPRINGBORO, OH 45066	HOMEMAKER	01/13/11	$250
MONSOUR, JILL SPRINGBORO, OH 45066	HOMEMAKER	04/14/11	$250
MORRA, MARCUS BRIDGEWATER, VA 22812	ROCKINGHAM MEMORIAL HOSPITAL	02/03/11	$250
MORRA, MARCUS BRIDGEWATER, VA 22812	ROCKINGHAM MEMORIAL HOSPITAL	04/19/11	$250
MOYER, CHRIS ENOLA, PA 17025	UCPA	01/18/11	$250
MOYER, CHRIS ENOLA, PA 17025	UCPA	05/04/11	$250
MOYER, JAMES E. STROUDSBURG, PA 18301	UROLOGY ASSOC OF POCONOS	01/18/11	$250
MOYER, JAMES E. STROUDSBURG, PA 18301	UROLOGY ASSOC OF POCONOS	04/12/11	$250
11:CV-10090	ARIZONA UROLOGY SPECIALISTS	06/29/11	$250

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NELSON, ROSCOE SCOTTSDALE, AZ 85255			
NIEMCZYK, PETER PHOENIX, AZ 85028	CENTER OF SEXUAL URINARY FUNC.	02/03/11	$250
NIEMCZYK, PETER PHOENIX, AZ 85028	CENTER OF SEXUAL URINARY FUNC.	04/26/11	$250

METHODOLOGY: The numbers on this page are based on contributions from individuals giving $200 or more, as reported to the Federal Election Commission.

NOTE: All the numbers on this page are for the 2012 election cycle and based on Federal Election Commission data released on March 25, 2013.

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HON VICTORIA ROBERTS

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American Kidney Stone Management

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Contrib	Occupation	Date	Amount
SWEENEY, PATRICK BATTLE CREEK, MI 49015	UROLOGY ASSOCIATES/UROLOGIST	10/31/11	$250
TAUB, HARVEY OCALA, FL 34471	CENTRAL FL UROLOGY SPECIALISTS/UROL	07/15/11	$250
TAUB, HARVEY OCALA, FL 34471	CENTRAL FL UROLOGY SPECIALISTS/UROL	11/22/11	$250
TAVASSOLI, TAGHI PARADISE VALLEY, AZ 85253	CMG/UROLOGIST	08/02/11	$250
TAVASSOLI, TAGHI PARADISE VALLEY, AZ 85253	CMG/UROLOGIST	10/18/11	$250
TAY, HOWARD PARADISE VALLEY, LA 85253	ARIZONA UROLOGY SPECIALISTS/UROLOGI	07/28/11	$250
TAYLOR, ROBERT S BATON ROUGE, LA 70868	LA UROLOGY/MD	09/08/11	$250
TELANG, DINESH JOHN GROSSE POINTE PARK, MI 48230	GROSSE POINTE UROLOGY/MEDICAL DOCTO	07/20/11	$250
TELANG, DINESH JOHN GROSSE POINTE PARK, MI 48230	GROSSE POINTE UROLOGY/MEDICAL DOCTO	10/31/11	$250
THOMPSON, DAVID E GRAND RAPIDS, MI 49525	UROLOGY SURGEONS PC/PHYSICIAN	07/20/11	$250
THOMPSON, DAVID E GRAND RAPIDS, MI 49525	UROLOGY SURGEONS PC/PHYSICIAN	10/31/11	$250
VANWYCK, KRISTEN NEWAYGO, MI 49337	NEWAYGO COUNTY/LEGAL SECRETARY	07/20/11	$250
LEVRAN, ZVI FARMINGTON HILLS, MI 48331	DR. ZVI LEVRAN, MD PC/UROLOGIST	07/20/11	$250
LEVRAN, ZVI FARMINGTON HILLS, MI 48331	DR. ZVI LEVRAN, MD PC/UROLOGIST	10/31/11	$250
LIFSON, BARRY WILLIAMSTOWN, WV 26187	MID OHIO VALLEY MEDICAL GROUP/PHYSI	07/26/11	$250
LIFSON, BARRY WILLIAMSTOWN, WV 26187	MID OHIO VALLEY MEDICAL GROUP/PHYSI	10/16/11	$250
LIM, KENNETH WEST BLOOMFIELD, MI 48323	OAKLAND COUNTY UROLOGISTS/PHYSICIAN	07/20/11	$250

LIM, KENNETH WEST BLOOMFIELD, MI 48323	OAKLAND COUNTY UROLOGISTS/PHYSICIAN	10/31/11	$250
LIPSON, ROBERT PHOENIX, AZ 85018	SCOTTSDALE UROLOGIC SURGEONS/UROLOG	08/02/11	$250
LIPSON, ROBERT PHOENIX, AZ 85018	SCOTTSDALE UROLOGIC SURGEONS/UROLOG	10/18/11	$250
LANGFORD, TIM D LITTLE ROCK, AR 72223	ARKANSAS UROLOGY/UROLOGIST	07/20/11	$250
LANGFORD, TIM D LITTLE ROCK, AR 72223	ARKANSAS UROLOGY/UROLOGIST	10/25/11	$250
LEBOVITCH, STEVE FT. LEE, NJ 07024	UROLOGY INSTITUTE NJ/PHYSICIAN	07/22/11	$250
LEBOVITCH, STEVE FT. LEE, NJ 07024	UROLOGY INSTITUTE NJ/PHYSICIAN	10/18/11	$250
KOPCHICK, JOHN GRAND RAPIDS, MI 49546	FAMILY UROLOGY ASSOCIATES, PLC/UROL	07/20/11	$250
KOPCHICK, JOHN GRAND RAPIDS, MI 49546	FAMILY UROLOGY ASSOCIATES, PLC/UROL	10/31/11	$250
KORMAN, HOWARD SOUTHFIELD, MI 48034	COMPREHENSIVE UROLOGY/DOCTOR	07/20/11	$250
KORMAN, HOWARD SOUTHFIELD, MI 48034	COMPREHENSIVE UROLOGY/DOCTOR	10/31/11	$250
KRIEGEL, JOEL BLOOMFIELD HILLS, MI 48304	THE UROLOGY CENTER/MD	07/20/11	$250
KRIEGEL, JOEL BLOOMFIELD HILLS, MI 48304	THE UROLOGY CENTER/MD	10/31/11	$250
KRUMHOLTZ, BARRY PARADISE VALLEY, AZ 85253	CIGNA MEDICAL GROUP/PHYSICIAN	08/02/11	$250
KRUMHOLTZ, BARRY PARADISE VALLEY, AZ 85253	CIGNA MEDICAL GROUP/PHYSICIAN	10/18/11	$250
KUBRITCH, WILLIAM BATON ROUGE, LA 70806	LA UROLOGY/UROLOGIST	09/08/11	$250
KUHN, RON G ROLAND, AR 72135	ARKANSAS UROLOGY/PHYSICIAN	07/20/11	$250
KUHN, RON G ROLAND, AR 72135	ARKANSAS UROLOGY/PHYSICIAN	10/25/11	$250
KUMAR, UDAYA HERNANDO, FL 34442	CENTRAL FL UROLOGY SPECIALISTS/UROL	07/15/11	$250
KUMAR, UDAYA HERNANDO, FL 34442	CENTRAL FL UROLOGY SPECIALISTS/UROL	11/22/11	$250
KING, EDWARD OCALA, FL 34471	CENTRAL FL UROLOGY SPECIALISTS/UROL	07/15/11	$250
KING, EDWARD OCALA, FL 34471	CENTRAL FL UROLOGY SPECIALISTS/UROL	11/22/11	$250
KLETSCHER, BRUCE SCOTTSDALE, AZ 85260	UROLOGY ASSOCIATES/UROLOGIST	08/02/11	$250
KLETSCHER, BRUCE SCOTTSDALE, AZ 85260	UROLOGY ASSOCIATES/UROLOGIST	10/18/11	$250
KNIGHT, EMERSON DR HARRISBURG, PA 17111	UROLOGY OF CENTRAL PA/PHYSICIAN	07/20/11	$250
11:CV-10090	DELTA MEDIX UROLOGY/PHYSICIAN	07/20/11	$250

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KOHN, IRA CLARK SUMMIT, PA 18411			
KOHN, IRA CLARK SUMMIT, PA 18411	DELTA MEDIX UROLOGY/PHYSICIAN	11/01/11	$250
KOI, PHILLIP SCOTTSDALE, AZ 85255	ARIZONA UROLOGY SPECIALISTS/UROLOGI	07/28/11	$250
KOI, PHILLIP SCOTTSDALE, AZ 85255	ARIZONA UROLOGY SPECIALISTS/UROLOGI	11/03/11	$250
WHISNANT, ROBERT ROANOKE, VA 24018	UROLOGY ASSOC./UROLOGIST	08/04/11	$250
WHISNANT, ROBERT ROANOKE, VA 24018	UROLOGY ASSOC./UROLOGIST	10/18/11	$250
WILLS, THOMAS E BATON ROUGE, LA 70810	BR UROLOGY GROUP/UROLOGIST	09/08/11	$250
WILSON, DEB SCOTTSDALE, AZ 85260	UROLOGY ASSOCIATES/UROLOGIST	08/02/11	$250
WILSON, DEB SCOTTSDALE, AZ 85260	UROLOGY ASSOCIATES/UROLOGIST	10/18/11	$250
WISE, PHILLIP JEWISON, MI 49428	UROLOGIC CONSULTANTS/PHYSICIAN	07/20/11	$250
WISE, PHILLIP JEWISON, MI 49428	UROLOGIC CONSULTANTS/PHYSICIAN	10/31/11	$250
WORISCHECK, JOSEPH MESA, AZ 85207	SOUTHWEST UROLOGIC SPECIALISTS/PHYS	08/02/11	$250
WORISCHECK, JOSEPH MESA, AZ 85207	SOUTHWEST UROLOGIC SPECIALISTS/PHYS	10/18/11	$250
YANKE, BRENT TENAFLY, NJ 07670	UGNJ/PHYSICIAN	07/26/11	$250
YANKE, BRENT TENAFLY, NJ 07670	UGNJ/PHYSICIAN	10/11/11	$250
YEAMANS, JEFFREY GROSS POINTE PARK, MI 48230	GROSS POINTE UROLOGY/MEDICAL DOCTOR	07/20/11	$250
YEAMANS, JEFFREY GROSS POINTE PARK, MI 48230	GROSS POINTE UROLOGY/MEDICAL DOCTOR	10/31/11	$250
YELLE, ARMAHD DIGHTON, MA 02715	TAUNTON UROLOGIC ASSOCIATES/UROLOGI	08/02/11	$250
YELLE, ARMAHD DIGHTON, MA 02715	TAUNTON UROLOGIC ASSOCIATES/UROLOGI	10/18/11	$250
ZALESKI, CHARLES LEWISBURG, PA 17837	GEISINGER MEDICAL CENTER/UROLOGIST	07/22/11	$250
ZALESKI, CHARLES LEWISBURG, PA 17837	GEISINGER MEDICAL CENTER/UROLOGIST	10/28/11	$250
ZARUSKI, ANDREW BATON ROUGE, LA 70817	BATON ROUGE CLINIC/PHYSICIAN	09/08/11	$250
ZEIDMAN, ERIC PHOENIX, AZ 85018	UROLOGY ASSOCIATES/UROLOGIST	08/02/11	$250
ZEIDMAN, ERIC PHOENIX, AZ 85018	UROLOGY ASSOCIATES/UROLOGIST	10/18/11	$250
ZELNERONOK, NICHOLAI CRYSTAL RIVER, FL 34429	CITRUS UROLOGY ASSOCIATES/UROLOGIST	07/15/11	$250
11:CV-10090	CITRUS UROLOGY ASSOCIATES/UROLOGIST	11/22/11	$250

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ZELNERONOK, NICHOLAI CRYSTAL RIVER, FL 34429			
AGARWAL, SAURABH HO HO KUS, NJ 07423	UROLOGY GROUP	02/03/11	$250
AGARWAL, SAURABH HO HO KUS, NJ 07423	UROLOGY GROUP	04/26/11	$250

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American Kidney Stone Management

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Contrib	Occupation	Date	Amount
ORLAND, STEVEN YARDLEY, PA 19067	PREMIER UROLOGY ASSOCIATES	04/26/11	$250
OWEN, SCOTT DR HARRISBURG, PA 17112	UCPA	01/18/11	$250
OWEN, SCOTT DR HARRISBURG, PA 17112	UCPA	05/04/11	$250
PARIHAR, HARDEY WEIRTON, WV 26062	PARIHAR MEDICAL GROUP	04/12/11	$250
PATEL, BIREN GLENDALE, AZ 85308	BIREN G. PATEL, MD PC	02/03/11	$250
PATEL, BIREN GLENDALE, AZ 85308	BIREN G. PATEL, MD PC	04/26/11	$250
PAULK, JACK OCALA, FL 34471	CENTRAL FL UROLOGY SPECIALISTS	01/25/11	$250
PAULK, JACK OCALA, FL 34471	CENTRAL FL UROLOGY SPECIALISTS	05/04/11	$250
PETERS, KENNETH HUNTINGTON WOODS, MI 48070	WILLIAM BEAUMONT HOSPITAL	01/25/11	$250
PETERS, KENNETH HUNTINGTON WOODS, MI 48070	WILLIAM BEAUMONT HOSPITAL	04/12/11	$250
PEWITT, BRADLEY NEW ALBANY, OH 43054	COUG	01/13/11	$250
PEWITT, BRADLEY NEW ALBANY, OH 43054	COUG	04/14/11	$250
PFEFFER, DAVID WERRERTER, VA 20186	UROLOGIC ASSOC. OF PIEDMONT PC	02/03/11	$250
PFEFFER, DAVID WERRERTER, VA 20186	UROLOGIC ASSOC. OF PIEDMONT PC	04/19/11	$250
POFFENBERGER, ROD ROANOKE, VA 24018	JEFFERSON SURGICAL CLINIC	02/03/11	$250
POFFENBERGER, ROD ROANOKE, VA 24018	JEFFERSON SURGICAL CLINIC	04/19/11	$250
PONAS, STEVEN SCOTTSDALE, AZ 85254	AFFILIATED UROLOGISTS	01/27/11	$250

PONAS, STEVEN SCOTTSDALE, AZ 85254	AFFILIATED UROLOGISTS	04/26/11	$250
RAMEY, JOHN ROBERT CLARK SUMMIT, PA 18411	DELTA MEDIX UROLOGY	01/18/11	$250
RAMEY, JOHN ROBERT CLARK SUMMIT, PA 18411	DELTA MEDIX UROLOGY	04/12/11	$250
RITTENBERG, MICHAEL SHAVERTOWN, PA 18708	RIVERVIEW UROLOGIC ASSOC	01/18/11	$250
RITTENBERG, MICHAEL SHAVERTOWN, PA 18708	RIVERVIEW UROLOGIC ASSOC	04/12/11	$250
ROBERTS, SHELDON CAVE CREEK, AZ 85331	BANNER ARIZONA MEDICAL CLINIC	02/03/11	$250
ROBERTS, SHELDON CAVE CREEK, AZ 85331	BANNER ARIZONA MEDICAL CLINIC	04/26/11	$250
ROCKOFF, STEVEN WILLIAMSPORT, PA 17701	SUSQUEHANNA UROLOGICAL ASSOC.	01/25/11	$250
ROCKOFF, STEVEN WILLIAMSPORT, PA 17701	SUSQUEHANNA UROLOGICAL ASSOC.	04/19/11	$250
RODRIGUEZ, HECTOR PLYMOUTH, MI 48170	ADVANCE UROLOGY	04/12/11	$250
ROELOF, BRIAN GRAND RAPIDS, MI 49503	UROLOGIC CONSULTANTS	01/25/11	$250
ROELOF, BRIAN GRAND RAPIDS, MI 49503	UROLOGIC CONSULTANTS	04/12/11	$250
ROME, SERGEY WYCKOFF, NJ 07481	UROLOGIC INSTITUTE NJ	02/03/11	$250
ROME, SERGEY WYCKOFF, NJ 07481	UROLOGIC INSTITUTE NJ	04/26/11	$250
ROSENBURG, BRADLEY WEST BLOOMFIELD, MI 48323	COMPREHENSIVE MEDICAL CENTER	04/12/11	$250
RUBENS, BRANDON PORTAGE, MI 49024	HEALTHCARE MIDWEST	01/25/11	$250
RUBENS, BRANDON PORTAGE, MI 49024	HEALTHCARE MIDWEST	04/12/11	$250
RUBENSTEIN, RON HUNTINGTON WOODS, MI 48070	CMC	01/25/11	$250
RUBENSTEIN, RON HUNTINGTON WOODS, MI 48070	CMC	04/12/11	$250
RUSNACK, SUSAN PARAMUS, NJ 07652	UROLOGIC INSTITUTE NJ	02/03/11	$250
RUSNACK, SUSAN PARAMUS, NJ 07652	UROLOGIC INSTITUTE NJ	04/26/11	$250
RUSSELL, BYRON DALE SCOTTSDALE, AZ 85259	SCOTTSDALE UROLOGIC SURGEONS	01/27/11	$250
RUSSELL, BYRON DALE SCOTTSDALE, AZ 85259	SCOTTSDALE UROLOGIC SURGEONS	04/26/11	$250
RUSSELL, SCOTT WAYNESVILLE, OH 45068	DAYTON PHYSICIANS, LLC	01/13/11	$250
RUSSELL, SCOTT WAYNESVILLE, OH 45068	DAYTON PHYSICIANS, LLC	04/14/11	$250
11-CV-10090	ARIZONA UROLOGY SPECIALISTS	02/03/11	$250

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SADEGHI, FARSHID SCOTTSDALE, AZ 85259			
SADEGHI, FARSHID SCOTTSDALE, AZ 85259	ARIZONA UROLOGY SPECIALISTS	04/26/11	$250
SALISZ, JOSEPH NORTON SHORES, MI 49441	WESTSHORE UROLOGY	01/25/11	$250
SALISZ, JOSEPH NORTON SHORES, MI 49441	WESTSHORE UROLOGY	04/12/11	$250
SARAZEN, ARNOLD SAUNDERSTOWN, RI 02874	UROLOGY ASSOCIATES INC.	04/19/11	$250
MAYS, SPYRIE D BATON ROUGE, LA 70806	SPYRIE D. MAYS MC, FACS/UROLOGIST	09/08/11	$250
MCDEVITT, WILLIAM LAKE ORION, MI 48362	OAKLAND COUNTY UROLOGISTS/PHYSICIAN	07/20/11	$250
MCDEVITT, WILLIAM LAKE ORION, MI 48362	OAKLAND COUNTY UROLOGISTS/PHYSICIAN	10/31/11	$250
MENDOZA, DAVID PARKERSBURG, WV 26104	MID OHIO VALLEY MEDICAL GROUP/UROLO	07/26/11	$250
MENDOZA, DAVID PARKERSBURG, WV 26104	MID OHIO VALLEY MEDICAL GROUP/UROLO	10/16/11	$250
MERTZ, THOMAS ROSEVILLE, MI 48066	GROSSE POINTE UROLOGY/PHYSICIAN	07/20/11	$250
MERTZ, THOMAS ROSEVILLE, MI 48066	GROSSE POINTE UROLOGY/PHYSICIAN	10/31/11	$250
MONSOUR, JILL SPRINGBORO, OH 45066	NONE/HOMEMAKER	08/23/11	$250
MONSOUR, JILL SPRINGBORO, OH 45066	NONE/HOMEMAKER	10/18/11	$250
MOONEY, D KEITH LITTLE ROCK, AR 72212	ARKANSAS UROLOGY/PHYSICIAN	07/20/11	$250
MOONEY, D KEITH LITTLE ROCK, AR 72212	ARKANSAS UROLOGY/PHYSICIAN	10/25/11	$250
MORRA, MARCUS BRIDGEWATER, VA 22812	ROCKINGHAM MEMORIAL HOSPITAL/UROLOG	08/04/11	$250
MORRA, MARCUS BRIDGEWATER, VA 22812	ROCKINGHAM MEMORIAL HOSPITAL/UROLOG	10/18/11	$250
MOYER, CHRIS ENOLA, PA 17025	UCPA/UROLOGIST	07/20/11	$250
MOYER, CHRIS ENOLA, PA 17025	UCPA/UROLOGIST	10/16/11	$250
MOYER, JAMES E. STROUDSBURG, PA 18301	UROLOGY ASSOC OF POCONOS/UROLOGIST	07/20/11	$250
MOYER, JAMES E. STROUDSBURG, PA 18301	UROLOGY ASSOC OF POCONOS/UROLOGIST	11/01/11	$250
NELSON, ROSCOE SCOTTSDALE, AZ 85255	ARIZONA UROLOGY SPECIALISTS/UROLOGI	12/08/11	$250
NIEMCZYK, PETER PHOENIX, AZ 85028	CENTER OF SEXUAL URINARY FUNC./UROL	08/02/11	$250
NIEMCZYK, PETER PHOENIX, AZ 85028	CENTER OF SEXUAL URINARY FUNC./UROL	10/18/11	$250
11:CV-10090	MD	07/22/11	$250

HON VICTORIA ROBERTS

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SURACI, ALDO MIFFLINVILLE, PA 18631			
SURACI, ALDO MIFFLINVILLE, PA 18631	MD	10/28/11	$250
SWEENEY, PATRICK BATTLE CREEK, MI 49015	UROLOGY ASSOCIATES/UROLOGIST	07/20/11	$250

METHODOLOGY: The numbers on this page are based on contributions from individuals giving $200 or more, as reported to the Federal Election Commission.

NOTE: All the numbers on this page are for the 2012 election cycle and based on Federal Election Commission data released on March 25, 2013.

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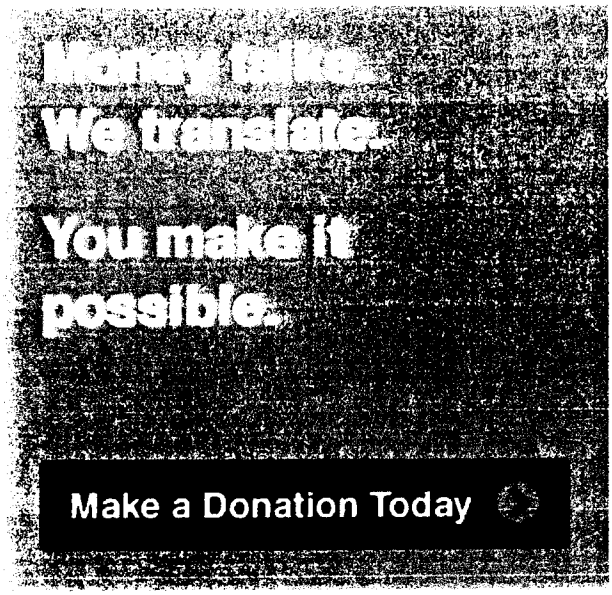

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Street City, State Zip Code

11:CV-10090

HON VICTORIA ROBERTS

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American Kidney Stone Management

Select a Cycle: 2012

Individual donors gave 992 large ($200+) contributions to this PAC in 2011-2012.

View

Browse by Amount: ... ...

D'AMICO, FRANK DR HUMMELSTOWN, PA 17306	UCPA	01/18/11 $250
D'AMICO, FRANK DR HUMMELSTOWN, PA 17306	UCPA	05/04/11 $250
DAITCH, JAMES PARADISE VALLEY, AZ 85253	ARIZONA UROLOGY SPECIALISTS	01/27/11 $250
DAITCH, JAMES PARADISE VALLEY, AZ 85253	ARIZONA UROLOGY SPECIALISTS	04/26/11 $250
DAVIDSON, WILLIAM NORTHVILLE, MI 48166	ARNKOFF-WEIGLER P.C.	01/25/11 $250
DAVIDSON, WILLIAM NORTHVILLE, MI 48166	ARNKOFF-WEIGLER P.C.	04/12/11 $250
DE GUZMAN, JOSE PHOENIX, AZ 85014	DMG	02/03/11 $250
DE GUZMAN, JOSE PHOENIX, AZ 85014	DMG	04/26/11 $250
DEL GAUDIO, WALTER SHAVERTOWN, PA 18708	UROLOGY ASSOCIATES KINGSTON	01/18/11 $250
DEL GAUDIO, WALTER SHAVERTOWN, PA 18708	UROLOGY ASSOCIATES KINGSTON	04/12/11 $250
DERSCH, MARK OCALA, FL 34480	CENTRAL FL UROLOGY SPECIALISTS	01/25/11 $250
DERSCH, MARK OCALA, FL 34480	CENTRAL FL UROLOGY SPECIALISTS	05/04/11 $250
DESAI, PARESH CRYSTAL RIVER, FL 34428	CENTRAL FL UROLOGY SPECIALISTS	01/25/11 $250
DESAI, PARESH CRYSTAL RIVER, FL 34428	CENTRAL FL UROLOGY SPECIALISTS	05/04/11 $250
DESAUTEL, MICHAEL IVERNESS, FL 34450	CENTRAL FL UROLOGY SPECIALISTS	01/25/11 $250
DESAUTEL, MICHAEL IVERNESS, FL 34450	CENTRAL FL UROLOGY SPECIALISTS	05/04/11 $250
DIAZ, EDWIN LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	01/25/11 $250

DIAZ, EDWIN LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	04/14/11	$250
DRABIK, BRIAN MCBAIN, MI 49601	UROLOGIST	04/12/11	$250
DUGAN, PATRICK DR MINERAL WELLS, WV 26150	MID OHIO VALLEY MEDICAL GROUP	02/28/11	$250
DUGAN, PATRICK DR MINERAL WELLS, WV 26150	MID OHIO VALLEY MEDICAL GROUP	04/12/11	$250
DUSSINGER, ANDREW DR ENOLA, PA 17025	CARLISLE REGIONAL MED. CENTER	01/18/11	$250
DUSSINGER, ANDREW DR ENOLA, PA 17025	CARLISLE REGIONAL MED. CENTER	05/04/11	$250
EUGEMIO, MICHAEL STROUDSBURG, PA 18360	UROLOGY ASSOC. OF POCONOS	04/12/11	$250
FENG, ADRIAN SCOTTSDALE, AZ 85266	UROLOGY ASSOCIATES	02/03/11	$250
FENG, ADRIAN SCOTTSDALE, AZ 85266	UROLOGY ASSOCIATES	04/26/11	$250
FIORELLI, ROBERT SHAVERTOWN, PA 18708	FIORELLI UROLOGY	01/18/11	$250
FIORELLI, ROBERT SHAVERTOWN, PA 18708	FIORELLI UROLOGY	04/12/11	$250
GALDIERI, LOUIS DR MORRISTOWN, NJ 07860	UROLOGY GROUP OF NEW JERSEY	01/31/11	$250
GALDIERI, LOUIS DR MORRISTOWN, NJ 07860	UROLOGY GROUP OF NEW JERSEY	04/19/11	$250
GAMBER, JEFF SCOTTSDALE, AZ 85262	PHOENIX UROLOGICAL SURGEONS	02/03/11	$250
GAMBER, JEFF SCOTTSDALE, AZ 85262	PHOENIX UROLOGICAL SURGEONS	04/26/11	$250
GARVIN, DENNIS ROANOKE, VA 24019	MD	02/03/11	$250
GARVIN, DENNIS ROANOKE, VA 24019	MD	04/19/11	$250
GBUREK, BERNARD SCOTTSDALE, AZ 85260	ARIZONA UROLOGY SPECIALISTS	01/27/11	$250
GBUREK, BERNARD SCOTTSDALE, AZ 85260	ARIZONA UROLOGY SPECIALISTS	04/26/11	$250
GILBERT, JERALD DALTON, PA 18414	DELTA MEDIX UROLOGY	01/18/11	$250
GILBERT, JERALD DALTON, PA 18414	DELTA MEDIX UROLOGY	04/12/11	$250
GIRGIS, SITY BLOOMFIELD HILLS, MI 48302	UROLOGIST	04/12/11	$250
GMYREK, GLENN MIDLAND PARK, NJ 07432	UROLOGY SPECIALTY CARE	02/03/11	$250
GMYREK, GLENN MIDLAND PARK, NJ 07432	UROLOGY SPECIALTY CARE	04/26/11	$250
GOLDBERG, SAMUEL TEMPE, AZ 85284	PHYSICIAN	01/27/11	$250
11:CV-10090	PHYSICIAN	04/26/11	$250

HON VICTORIA ROBERTS

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GOLDBERG, SAMUEL TEMPE, AZ 85284			
GOLDMAN, IAN SCOTTSDALE, AZ 85262	IAN L. GOLDMAN, MD PC	02/03/11	$250
GOLDMAN, IAN SCOTTSDALE, AZ 85262	IAN L. GOLDMAN, MD PC	04/26/11	$250
GONZALEZ, JOSE BEVERLY HILLS, MI 48025	COMPREHENSIVE UROLOGY	01/25/11	$250
GONZALEZ, JOSE BEVERLY HILLS, MI 48025	COMPREHENSIVE UROLOGY	04/12/11	$250
GOODSON, TIMOTHY LITTLE ROCK, AR 72207	ARKANSAS UROLOGY	01/25/11	$250
GOODSON, TIMOTHY LITTLE ROCK, AR 72207	ARKANSAS UROLOGY	04/14/11	$250
GORDON, BARRY TEMPE, AZ 85284	UROLOGIC CONSULTANTS, PC	01/27/11	$250
GORDON, BARRY TEMPE, AZ 85284	UROLOGIC CONSULTANTS, PC	04/26/11	$250
GRAHAM, SAM MANAKIN SABOT, PA 23103	HCA	04/19/11	$250
GRISSOM, ROBERT T BATON ROUGE, LA 70808	LOUISIANA UROLOGY, LLC	06/11/11	$250
GRONKIEWICZ, BRUCE DR CARLISLE, PA 17013	WATERSHED UROLOGY	01/18/11	$250
GRONKIEWICZ, BRUCE DR CARLISLE, PA 17013	WATERSHED UROLOGY	05/04/11	$250
GROSSKLAUS, DAVID MESA, AZ 85213	DAVID J. GROSSKLAUS, MD PC	02/03/11	$250
GROSSKLAUS, DAVID MESA, AZ 85213	DAVID J. GROSSKLAUS, MD PC	04/26/11	$250
HAN, KEN-RYU PHOENIX, AZ 85085	ARIZONA UROLOGY SPECIALISTS	06/29/11	$250
HANSEN, JOHN JR PHOENIX, AZ 85023	SUN VALLEY UROLOGY PC	02/03/11	$250
HANSEN, JOHN JR PHOENIX, AZ 85023	SUN VALLEY UROLOGY PC	04/26/11	$250
HAROLD, DAVID D WEST BLOOMFIELD, MI 48341	DAVID L. HAROLD MD, PC	01/25/11	$250
HAROLD, DAVID D WEST BLOOMFIELD, MI 48341	DAVID L. HAROLD MD, PC	04/12/11	$250
HARTANTO, VICTOR H MAHWAH, NJ 07430	UROLOGY GROUP OF PA	02/03/11	$250
HARTANTO, VICTOR H MAHWAH, NJ 07430	UROLOGY GROUP OF PA	04/26/11	$250
HASTINGS, DAVID BATON ROUGE, LA 70810	LA UROLOGY	06/11/11	$250
HEFFERNAN, JOHN JAMESTOWN, RI 02835	UROLOGY ASSOCIATES INC.	04/19/11	$250
HELLAND, MARLOU GILBERT, AZ 85234	UROLOGIC HEALTH ASSOCIATES	02/03/11	$250
11-CV-10090	UROLOGIC HEALTH ASSOCIATES	04/26/11	$250

HON VICTORIA ROBERTS

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HELLAND, MARLOU GILBERT, AZ 85234			
HICKS, CHRISTOPHER HUDDLESTON, VA 24104	UROLOGIC SURGERY	02/03/11	$250
HICKS, CHRISTOPHER HUDDLESTON, VA 24104	UROLOGIC SURGERY	04/19/11	$250

METHODOLOGY: The numbers on this page are based on contributions from individuals giving $200 or more as reported to the Federal Election Commission.

NOTE: [illegible]

Commission data released on March 25, 2013.

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HON VICTORIA ROBERTS

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American Kidney Stone Management

- Summary
- Recipients
- Donors
- Expenditures
- PAC to PAC/Party

Select a Cycle: 2012

Individual donors gave 992 large ($200+) contributions to this PAC in 2011-2012.

View Top Organizations

Browse by Amount: Previous1 ...23456 ...15Next

Contrib	Occupation	Date	Amount
ALEXANDER, ERIK SCOTTSDALE, AZ 85259	MD	01/27/11	$250
ALEXANDER, ERIK SCOTTSDALE, AZ 85259	MD	04/26/11	$250
ANEMA, JOHN CALEDONIA, MI 49316	UROLOGIC CONSULTANTS	01/25/11	$250
ANEMA, JOHN CALEDONIA, MI 49316	UROLOGIC CONSULTANTS	04/12/11	$250
ANNALORO, ANGELO BATON ROUGE, LA 70808	BATON ROUGE UROLOGY GROUP	06/11/11	$250
ARGUESO, LUIS PHOENIX, AZ 85018	PEDIATRIC UROLOGY ASSOCIATED	01/27/11	$250
ARGUESO, LUIS PHOENIX, AZ 85018	PEDIATRIC UROLOGY ASSOCIATED	04/26/11	$250
BAILEY, ROBERT PHOENIX, AZ 85018	PEDIATRIC UROLOGY ASSOCIATED	01/27/11	$250
BAILEY, ROBERT PHOENIX, AZ 85018	PEDIATRIC UROLOGY ASSOCIATED	04/26/11	$250
BARRETT, RONALD WAVERLY, PA 18471	DELTA MEDIX UROLOGY	01/18/11	$250
BARRETT, RONALD WAVERLY, PA 18471	DELTA MEDIX UROLOGY	04/12/11	$250
BATES, ROBERT ZEELAND, MI 49464	HOLLAND HOSPITAL	04/12/11	$250
BELIS, JOHN DR HARRISBURG, PA 17112	UCPA	01/18/11	$250
BELIS, JOHN DR HARRISBURG, PA 17112	UCPA	05/04/11	$250
BENSON, JACK CAREFEE, AZ 85377	PHOENIX UROLOGICAL SURGEONS	01/27/11	$250
BENSON, JACK CAREFEE, AZ 85377	PHOENIX UROLOGICAL SURGEONS	04/26/11	$250
BETRUS, GLENN FORT GRATIOT, MI 48059	COMPREHENSIVE MED. CENTER PLLC	01/25/11	$250

BETRUS, GLENN FORT GRATIOT, MI 48059	COMPREHENSIVE MED. CENTER PLLC	04/12/11	$250
BHANGDIA, DARSHAN LEWISBURG, PA 17832	GEISENGER MEDICAL CENTER	01/25/11	$250
BHANGDIA, DARSHAN LEWISBURG, PA 17832	GEISENGER MEDICAL CENTER	04/19/11	$250
BIGELOW, KEVIN SCOTTSDALE, AZ 85260	CENTER FOR UROLOGICAL SERVICES	01/27/11	$250
BIGELOW, KEVIN SCOTTSDALE, AZ 85260	CENTER FOR UROLOGICAL SERVICES	04/26/11	$250
BLIX, GREGOR W KALAMAZOO, MI 49008	HEALTHCARE MIDWEST	01/25/11	$250
BLIX, GREGOR W KALAMAZOO, MI 49008	HEALTHCARE MIDWEST	04/12/11	$250
BLOCK, PAUL PHOENIX, AZ 85013	ARIZONA UROLOGY SPECIALISTS	06/29/11	$250
BLUE, KENNETH M III ST. FRANCISVILLE, LA 70775	LOUISIANA UROLOGY GROUP	06/11/11	$250
BOHNERT, WILLIAM PHOENIX, AZ 85018	ARIZONA UROLOGY SPECIALISTS	01/27/11	$250
BOHNERT, WILLIAM PHOENIX, AZ 85018	ARIZONA UROLOGY SPECIALISTS	04/26/11	$250
BOLINE, JOHN DR HUMMELSTOWN, PA 17036	UROLOGY OF CENTRAL PA	01/18/11	$250
BOLINE, JOHN DR HUMMELSTOWN, PA 17036	UROLOGY OF CENTRAL PA	05/04/11	$250
BOMBINO, PAUL PEORIA, AZ 85383	SUN VALLEY UROLOGY PC	04/26/11	$250
BORHAN, AL PARADISE VALLEY, AZ 85253	AFFILLIATED UROLOGIST	02/03/11	$250
BORHAN, AL PARADISE VALLEY, AZ 85253	AFFILLIATED UROLOGIST	04/26/11	$250
BOUR, JAMES B KALAMAZOO, MI 49008	HEATHCARE MIDWEST	01/25/11	$250
BOUR, JAMES B KALAMAZOO, MI 49008	HEATHCARE MIDWEST	04/12/11	$250
BRIDGES, CHARLIE BATON ROUGE, LA 70816	PHYSICIAN	06/11/11	$250
BRIZZOLARA, JOHN LITTLE ROCK, AR 72107	ARKANSAS UROLOGY	01/25/11	$250
BRIZZOLARA, JOHN LITTLE ROCK, AR 72107	ARKANSAS UROLOGY	04/14/11	$250
BUCKLEY, CARIE III STAUNTON, VA 24401	BLUE RIDGE UROLOGY	02/03/11	$250
BUCKLEY, CARIE III STAUNTON, VA 24401	BLUE RIDGE UROLOGY	04/19/11	$250
BURNS, CHARLES WYOMING, PA 18644	RIVERVIEW UROLOGY	04/12/11	$250
CADOFF, ROBERT SCOTTSDALE, AZ 85251	CENTER FOR UROLOGICAL SERVICES	01/27/11	$250
11-CV-10090 HON VICTORIA ROBERTS	CENTER FOR UROLOGICAL SERVICES	04/26/11	$250

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CADOFF, ROBERT SCOTTSDALE, AZ 85251			
CAESAR, RICHARD BARRINGTON, RI 02806	UROLOGIC PHYS. OF NEW ENGLAND	02/28/11	$250
CAESAR, RICHARD BARRINGTON, RI 02806	UROLOGIC PHYS. OF NEW ENGLAND	04/19/11	$250
CAMPBELL, TODD G GROSSE POINTE PARK, MI 48230	GROSSE POINTE UROLOGY	01/25/11	$250
CAMPBELL, TODD G GROSSE POINTE PARK, MI 48230	GROSSE POINTE UROLOGY	04/12/11	$250
CAMPO, RICHARD P WYCKOFF, NJ 07481	PHYSICIAN	02/03/11	$250
CAMPO, RICHARD P WYCKOFF, NJ 07481	PHYSICIAN	04/26/11	$250
CAROTHERS, GEORGE ADA, MI 49301	MICHIGAN UROLOGY CLINIC	01/25/11	$250
CAROTHERS, GEORGE ADA, MI 49301	MICHIGAN UROLOGY CLINIC	04/12/11	$250
CARROLL, JOHN C PORTSMOUTH, RI 02871	UROLOGY INC.	02/28/11	$250
CARROLL, JOHN C PORTSMOUTH, RI 02871	UROLOGY INC.	04/19/11	$250
CENTENERA, VIRGILIO DR CARLISLE, PA 17015	CARLISLE REGIONAL MED. CENTER	01/18/11	$250
CENTENERA, VIRGILIO DR CARLISLE, PA 17015	CARLISLE REGIONAL MED. CENTER	05/04/11	$250
CHOPRA, RAJ BLOOMSBURG, PA 17815	MEDICAL DOCTOR	04/12/11	$250
CHUNG, AUBREY PHOENIX, AZ 85023	SUN VALLEY UROLOGY PC	02/03/11	$250
CHUNG, AUBREY PHOENIX, AZ 85023	SUN VALLEY UROLOGY PC	04/26/11	$250
CLAYBROOK, KEVIN LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	01/25/11	$250
CLAYBROOK, KEVIN LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	04/14/11	$250
COURY, THOMAS FORT GRATIOT, MI 48059	UROLOGY ASSOC OF PORT HURON	01/25/11	$250
COURY, THOMAS FORT GRATIOT, MI 48059	UROLOGY ASSOC OF PORT HURON	04/12/11	$250
COUSSENS, DAVID LITTLE ROCK, AR 72211	ARKANSAS UROLOGY	01/25/11	$250
COUSSENS, DAVID LITTLE ROCK, AR 72211	ARKANSAS UROLOGY	04/14/11	$250
CROUSHORE, JOHN MESA, AZ 85204	ANTHEM MEDICAL MANAGEMENT	01/27/11	$250
CROUSHORE, JOHN MESA, AZ 85204	ANTHEM MEDICAL MANAGEMENT	04/26/11	$250
CUNNINGHAM, DAVID OCALA, FL 34471	CENTRAL FL UROLOGY SPECIALISTS	01/25/11	$250
11-CV-10090	CENTRAL FL UROLOGY SPECIALISTS	05/04/11	$250

HON VICTORIA ROBERTS

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CUNNINGHAM, DAVID OCALA, FL 34471			
CURRY, JON M GRAND RAPIDS, MI 49534	UROLOGIC CONSULTANTS	01/25/11	$250
CURRY, JON M GRAND RAPIDS, MI 49534	UROLOGIC CONSULTANTS	04/12/11	$250

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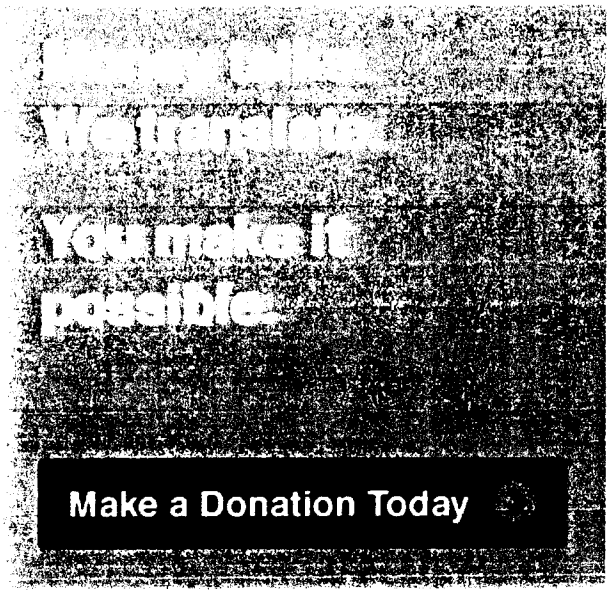

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Street City, State Zip Code

11:CV-10090

HON VICTORIA ROBERTS

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American Kidney Stone Management

Select a Cycle: 2012

Individual donors gave 992 large ($200+) contributions to this PAC in 2011-2012.

View

Browse by Amount: ... ...

HURLEY, PATRICK NOVI, MI 48375	MICHIGAN UROLOGICAL	04/12/11 $250
HURM, RAYMOND PHOENIX, AZ 85021	UROLOGY SPECIALISTS LTD.	01/27/11 $250
HURM, RAYMOND PHOENIX, AZ 85021	UROLOGY SPECIALISTS LTD.	04/26/11 $250
INGERMAN, ALEXANDER BATON ROUGE, LA 70810	THE BATON ROUGE CLINIC	06/11/11 $250
ISACKSEN, ROBERT R KALAMAZOO, MI 49008	HEALTHCARE MIDWEST	01/25/11 $250
ISACKSEN, ROBERT R KALAMAZOO, MI 49008	HEALTHCARE MIDWEST	04/12/11 $250
JACKS, DAVID C PINE BLUFF, AR 71603	PHYSICIAN	01/25/11 $250
JACKS, DAVID C PINE BLUFF, AR 71603	PHYSICIAN	04/14/11 $250
JANO, FARID BLOOMFIELD HILLS, MI 48304	PHYSICIAN	01/25/11 $250
JANO, FARID BLOOMFIELD HILLS, MI 48304	PHYSICIAN	04/12/11 $250
JAYACHANDRAN, S PARADISE VALLEY, AZ 85253	NORTHWEST UROLOGY ASSOCIATES	01/27/11 $250
JAYACHANDRAN, S PARADISE VALLEY, AZ 85253	NORTHWEST UROLOGY ASSOCIATES	04/26/11 $250
JO, PAUL OCALA, FL 34471	CENTRAL FL UROLOGY SPECIALISTS	01/25/11 $250
JO, PAUL OCALA, FL 34471	CENTRAL FL UROLOGY SPECIALISTS	05/04/11 $250
JONES, WILLIAM LYNDHURST, VA 22952	BLUE RIDGE UROLOGY	02/03/11 $250
JONES, WILLIAM LYNDHURST, VA 22952	BLUE RIDGE UROLOGY	04/19/11 $250
KACHEL, THOMAS MECHANICSBURG, PA 17050	UROLOGY OF CENTRAL PA	05/04/11 $250

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HON VICTORIA ROBERTS

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KAGEY, DAVID ROANOKE, VA 24018	UROLOGY ASSOC.	02/03/11	$250
KAGEY, DAVID ROANOKE, VA 24018	UROLOGY ASSOC.	04/19/11	$250
KAMER, MARSHALL FT. GRATIOT, MI 48059	UROLOGY ASSOC OF PORT HURON	01/25/11	$250
KAMER, MARSHALL FT. GRATIOT, MI 48059	UROLOGY ASSOC OF PORT HURON	04/12/11	$250
KAPNER, JAMIE SCOTTSDALE, AZ 85259	MD	01/27/11	$250
KAPNER, JAMIE SCOTTSDALE, AZ 85259	MD	04/26/11	$250
KASS, EVAN ROYAL OAK, MI 48067	COMPREHENSIVE MED. CENTER PLLC	01/25/11	$250
KASS, EVAN ROYAL OAK, MI 48067	COMPREHENSIVE MED. CENTER PLLC	04/12/11	$250
KATZ, GARY CHESPEAKE, VA 23320	UROLOGY OF VA	02/03/11	$250
KATZ, GARY CHESPEAKE, VA 23320	UROLOGY OF VA	04/19/11	$250
KAUFMAN, PAUL DR NEW ALBANY, OH 43054	CENTRAL OHIO UROLOGY GROUP	01/13/11	$250
KAYE, MITCHELL SCOTTSDALE, AZ 85255	SCOTTSDALE UROLOGIC SURGEONS	01/27/11	$250
KAYE, MITCHELL SCOTTSDALE, AZ 85255	SCOTTSDALE UROLOGIC SURGEONS	04/26/11	$250
KEOLEIAN, CHARLES BINHAM FARMS, MI 48025	COMPREHENSIVE MED. CENTER PLLC	01/25/11	$250
KEOLEIAN, CHARLES BINHAM FARMS, MI 48025	COMPREHENSIVE MED. CENTER PLLC	04/12/11	$250
KING, CHARLES OCALA, FL 34471	OCALA UROLOGY SPECIALISTS	01/25/11	$250
KING, CHARLES OCALA, FL 34471	OCALA UROLOGY SPECIALISTS	05/04/11	$250
KING, EDWARD OCALA, FL 34471	CENTRAL FL UROLOGY SPECIALISTS	01/25/11	$250
KING, EDWARD OCALA, FL 34471	CENTRAL FL UROLOGY SPECIALISTS	05/04/11	$250
KLETSCHER, BRUCE SCOTTSDALE, AZ 85260	UROLOGY ASSOCIATES	01/27/11	$250
KLETSCHER, BRUCE SCOTTSDALE, AZ 85260	UROLOGY ASSOCIATES	04/26/11	$250
KNIGHT, EMERSON DR HARRISBURG, PA 17111	UROLOGY OF CENTRAL PA	01/18/11	$250
KNIGHT, EMERSON DR HARRISBURG, PA 17111	UROLOGY OF CENTRAL PA	05/04/11	$250
KOHN, IRA CLARK SUMMIT, PA 18411	DELTA MEDIX UROLOGY	01/18/11	$250
KOHN, IRA CLARK SUMMIT, PA 18411	DELTA MEDIX UROLOGY	04/12/11	$250
11:CV-10090	ARIZONA UROLOGY SPECIALISTS	06/29/11	$250

HON VICTORIA ROBERTS

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KOI, PHILLIP SCOTTSDALE, AZ 85255			
KOPCHICK, JOHN GRAND RAPIDS, MI 49546	FAMILY UROLOGY ASSOCIATES, PLC	01/25/11	$250
KOPCHICK, JOHN GRAND RAPIDS, MI 49546	FAMILY UROLOGY ASSOCIATES, PLC	04/12/11	$250
KORMAN, HOWARD SOUTHFIELD, MI 48034	COMPREHENSIVE UROLOGY	01/25/11	$250
KORMAN, HOWARD SOUTHFIELD, MI 48034	COMPREHENSIVE UROLOGY	04/12/11	$250
KRIEGEL, JOEL BLOOMFIELD HILLS, MI 48304	THE UROLOGY CENTER	01/25/11	$250
KRIEGEL, JOEL BLOOMFIELD HILLS, MI 48304	THE UROLOGY CENTER	04/12/11	$250
KRUMHOLTZ, BARRY PARADISE VALLEY, AZ 85253	CIGNA MEDICAL GROUP	02/03/11	$250
KRUMHOLTZ, BARRY PARADISE VALLEY, AZ 85253	CIGNA MEDICAL GROUP	04/26/11	$250
KUBRITCH, WILLIAM BATON ROUGE, LA 70806	LA UROLOGY	06/11/11	$250
KUMAR, UDAYA HERNANDO, FL 34442	CENTRAL FL UROLOGY SPECIALISTS	01/25/11	$250
KUMAR, UDAYA HERNANDO, FL 34442	CENTRAL FL UROLOGY SPECIALISTS	05/04/11	$250
LANGFORD, TIM D LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	01/25/11	$250
LANGFORD, TIM D LITTLE ROCK, AR 72223	ARKANSAS UROLOGY	04/14/11	$250
LEBOVITCH, STEVE FT. LEE, NJ 07024	UROLOGY INSTITUTE NJ	02/03/11	$250
LEBOVITCH, STEVE FT. LEE, NJ 07024	UROLOGY INSTITUTE NJ	04/26/11	$250
LEVESQUE, PETER NORTH EASTON, MA 02356	TAUNTON UROLOGIC ASSOCIATES	03/09/11	$250
LEVRAN, ZVI FARMINGTON HILLS, MI 48331	DR. ZVI LEVRAN, MD PC	01/25/11	$250
LEVRAN, ZVI FARMINGTON HILLS, MI 48331	DR. ZVI LEVRAN, MD PC	04/12/11	$250
MACKEY, TIMOTHY J OAKLAND, NJ 07436	UROLOGY GROUP PA	12/27/12	$250
NIEDRACH, WILLIAM MEDFORD, NJ 08055	DELAWARE VALLEY UROLOGY LLC	12/20/12	$250
RUSNACK, SUSAN PARAMUS, NJ 07652	UROLOGIC INSTITUTE NJ	12/27/12	$250
SLAVICK, HARRIS VINELAND, PA 08361	HARRIS D. SLAVICK, MD PA	12/20/12	$250
THUR, PAUL BALA CYNWYD, PA 19004	DELAWARE VALLEY UROLOGY LLC	12/20/12	$250
WIXTED, WILLIAM M LINWOOD, NJ 08221	WILLIAM M. WIXTED, MD, PC	12/20/12	$250
11-CV-10090	UROLOGY GROUP/PHYSICIAN	07/22/11	$250

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AGARWAL, SAURABH HO HO KUS, NJ 07423			
AGARWAL, SAURABH HO HO KUS, NJ 07423	UROLOGY GROUP/PHYSICIAN	10/18/11	$250
ALEXANDER, ERIK SCOTTSDALE, AZ 85259	MD	08/02/11	$250

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ANEMA, JOHN CALEDONIA, MI 49316	UROLOGIC CONSULTANTS/UROLOGIST	10/31/11 $250
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ARGUESO, LUIS PHOENIX, AZ 85018	PEDIATRIC UROLOGY ASSOCIATED/UROLOG	10/18/11 $250
BAILEY, ROBERT PHOENIX, AZ 85018	PEDIATRIC UROLOGY ASSOCIATED/PHYSIC	08/02/11 $250
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BELIS, JOHN DR HARRISBURG, PA 17112	UCPA/M.D.	07/20/11 $250
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